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January 23, 2018

Via E-mail & First Class Mail

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Acting Director, Superfund Division
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77 West Jackson Blvd.
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Mr. Jeffrey Kimble
On-Scene Coordinator
USEPA Region 5
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Ms. C. Heidi Grether
Director
Michigan Department of Environmental
Quality
P.O. Box 30475
Lansing, MI 48909

Mr. David O'Donnell
Acting District Coordinator
Remediation and Redevelopment Division
Grand Rapids District Office
Department of Environmental Quality
350 Ottawa Avenue, NW, Unit 10
Grand Rapids, MI 49503-2341

Re: Deficiencies in Wolverine's Investigation and Response Activities.

Dear Mr. Kimble, Mr. O'Donnell, and Mr. Kaplan:

As you may know, our law firm represents hundreds of residents impacted by groundwater contamination emanating from Wolverine World Wide Inc.'s ("Wolverine") former disposal area at 1885 House Street (the "House Street Disposal Site") along with several other suspected unlicensed disposal areas in the vicinity. The contamination has caused diminution in residents' property values, medical issues, anxiety, stress, and numerous other costs and damages. We are encouraged that both the Michigan Department of Environmental Quality (the "MDEQ") and the United States Environmental Protection Agency (the "EPA") initiated actions against Wolverine to compel environmental investigation and response activities.¹ Because our clients have significant interests in proper investigation of the contaminated sites to protect their health and surrounding environment, we are writing to provide comments and additional information in response to Wolverine's current investigation and clean-up plans.

¹ The Complaint filed against Wolverine by the MDEQ in the United States District Court for the Western District of Michigan (Case #1:18-CV-00039) and the Unilateral Administrative Order for Removal Actions issued by the EPA to Wolverine (CERCLA Docket No. V-W-18-C-004).

I. Technical Commentary: Several Deficiencies Exist In Wolverine's Current Plans.

Enclosed as **Exhibit A** is a copy of a Technical Memorandum prepared by Mick Lynch of American Hydrogeology Corporation (AHC). Mick Lynch is a well-respected environmental consultant with over thirty-seven (37) years of experience in conducting systematic delineation of soil and groundwater contamination at contaminated properties. As you may be aware, to date, Wolverine has provided only cursory information of the environmental conditions at former disposal sites. The Technical Memorandum contains preliminary comments based on a review of the limited information that is currently available for review by AHC.

The Technical Memorandum identifies several deficiencies in Wolverine's currently proposed plans. We respectfully request that both agencies consider the comments and analysis set forth in the Technical Memorandum in analyzing any work plans to be submitted by Wolverine and its consultants.

II. Analytical Sampling Data Shows a Need for a More Robust Investigation and Monitoring Program.

We are also providing a copy of the analytical results from sampling performed by Fishbeck, Thompson, Carr & Huber, including the following samples: (1) soil samples from an adjacent property (south of the House Street Disposal Site) currently owned by the Michigan Department of Transportation (the "MDOT" Site), attached as **Exhibit B**; (2) soil samples from private property located along Imperial Pine Street, located to the west of the House Street Disposal Site (the "Imperial Pine Site"), attached as **Exhibit C**; and (3) groundwater samples from residential wells located in the vicinity of the House Street Disposal Site, attached as **Exhibit D**.

The above-referenced sampling data must be considered in the ongoing environmental investigation for several reasons:

A. Other Sites Must Be The Subject of Enforcement.

As evidenced by the sampling data above, Wolverine disposed of waste materials containing hazardous substances at locations beyond the boundaries of the House Street Disposal Area. As a result, any investigation of contamination caused by Wolverine should include an investigation of other illicit or unlicensed disposal sites in the vicinity of the House Street Disposal Site. The sites should include—at a minimum—the MDOT Site, the Imperial Pine Site, the dumping site(s) on or around the intersection of Jewell Ave. NE & 11 Mile Rd. NE, and the dumping site(s) on the east side of U.S. Highway 131 between 10 Mile Rd. NE and 11 Mile Rd. NE.

B. Wolverine Has Failed to Thoroughly Characterize Waste.

Wolverine removed waste materials from the MDOT Site and the Imperial Pine Site before adequate sampling had been performed to identify and delineate the entire contamination that may have been present, much less the concentrations or distribution of such contaminants.

Only limited sampling was performed to characterize waste materials for disposal. More thorough sampling of source areas prior to removal would have assisted in the development of a sampling plan to determine which contaminants may have migrated away from the site in groundwater.

This mistake should not be repeated. Before any additional removal activities are undertaken at the House Street Disposal Site or other surrounding unlicensed disposal areas, all source areas should be properly characterized and delineated (for PFAS and all other contaminants of concern).

C. Residential Wells Must Be Monitored For All Hazardous Substances Present, Not Just PFAS.

The sampling data establishes the presence of hazardous substances (other than PFAS) substantially above applicable cleanup criteria at the unlicensed disposal sites, including total chromium, hexavalent chromium, arsenic, mercury, selenium, lead, and zinc. It also shows that at least one home has already tested positive for the presence of lead at concentrations substantially above federal and state criteria for drinking water. Similar hazardous substances (and possibly other chemicals) undoubtedly are present at the House Street Disposal Site at similar or even higher concentrations, along with being present at Wolverine's other unlicensed dump sites in the vicinity.

Based on that data, monitoring of residential drinking wells should be expanded to address any and all contaminants identified at the MDOT Site, Imperial Pine Site, House Street Disposal Site, and other unlicensed disposal sites in the area. Such monitoring is necessary to protect our clients' and the public's health.

D. Residential Drinking Water Must Be Regularly Monitored.

A significant number of residential wells have been impacted by PFAS. Wolverine has taken only one PFAS water sample for some households. The MDEQ routinely requires quarterly sampling of groundwater in conjunction with required environmental response activities. The purpose of such quarterly sampling is presumably to account for fluctuations in contaminant concentrations (due to seasonal groundwater level changes, variability in concentrations of contamination that may be migrating from a source area, analytical errors, *etc.*). In fact, in January 2018, the second set of tests from several homes near the House Street Disposal Site tested positive for PFAS after originally testing negative. As a result, it is clear that a single isolated test is not adequate to determine that a residential drinking well has not been impacted by contamination.

A more thorough and comprehensive sampling procedure is warranted to avoid the risk that inadequate sampling failed to identify PFAS contamination that may have gone undetected in the initial round of residential well sampling. At the very least, all residential wells in the relevant testing areas should be re-sampled and analyzed on a quarterly basis. In the event a sampling protocol has already been established and submitted to the MDEQ or EPA, then we request a copy of that protocol for our clients' review.

III. PFAS should be included in a Hazard Ranking System Evaluation for National Priorities List.

The EPA's Unilateral Administrative Order for Removal Actions does not specifically address PFAS contamination, focusing instead on other "hazardous substances" under the Comprehensive Environmental Response, Compensation and Liability Act ("CERCLA"). However, the EPA should consider the impact of PFAS (including PFOA) in any evaluation of the site(s) under the EPA's Hazardous Ranking System ("HRS"), which is utilized by the agency to determine whether a site should be placed on the National Priorities List ("NPL"). The EPA has previously considered PFAS contamination in conducting a HRS evaluation at the Saint Gobain Performance Plastics Superfund Site. See Support Document for the Revised National Priorities List Final Rule – Saint-Gobain Performance Plastics (July 2017), **Exhibit E**.

The EPA Support Document attached explains why PFOA was utilized for the purposes of a HRS evaluation:

PFOA was correctly identified as qualifying as a CERCLA pollutant or contaminant at the SGPP site, not a CERCLA hazardous substance, and, therefore, can be considered in the HRS site evaluation, as explained below. Furthermore, there is no requirement that a drinking water standard must be promulgated for a substance for it to be included in an HRS evaluation, only that it meet the CERCLA definition of a pollutant or contaminant.

CERCLA Section 101(33) defines "pollutant or contaminant" as including but not limited to, any element, substance, compound, or mixture, including disease-causing agents, which after release into the environment and upon exposure, ingestion, inhalation, or assimilation into any organism, either directly from the environment or indirectly by ingestion through food chains, will or may reasonably be anticipated to cause death, disease, behavioral abnormalities, cancer, genetic mutation, physiological malfunctions (including malfunctions in reproduction) or physical deformations, in such organisms or their offspring.

Hazardous substances are defined for HRS purposes in HRS Section 1.1, *Definitions*, as, CERCLA hazardous substances, pollutants, and contaminants as defined in CERCLA sections 101(14) and 101(33), except where otherwise specifically noted in the HRS. [55 FR 51586, December 14, 1990].

Therefore, while a substance may not be a CERCLA hazardous substance, it can be considered a HRS hazardous substance because the HRS defines pollutants and contaminants to be HRS hazardous substances.

PFOA can be considered a pollutant or contaminant at this site because it is at a concentration at the Site that could cause increase total cholesterol, thyroid disease, decreased response to vaccines, and pregnancy-related hypertension or preeclampsia (pages 241 to 242, 253 to 257 of Reference 13, *Health Effects*

Support Document for Perfluorooctanoic Acid (PFOA) (EPA, 2016)). PFOA is clearly in the release from the SGPP facility. It was found in quantifiable levels in 2 of the 3 drinking water wells evaluated in the scoring of the Site. The PFOA concentration in a sample from PSW 7 was found to be 520 ng/L (0.52 µg/L), and the PFOA concentration in a sample from PSW 3 was found to be 140 ng/L (0.14 µg/L). PFOA has also been documented in monitoring wells at the Site at concentrations ranging from 570 ng/L to 18,000 ng/L (0.57µg/L to 18 µg/L) (pages 41 – 43 of the HRS documentation record at proposal).

See Support Document for the Revised National Priorities List Final Rule – Saint-Gobain Performance Plastics at 14-15 (emphasis added).

Based on the foregoing, as the EPA has done previously, PFAS/PFOA contamination should be considered for purposes of conducting a complete HRS evaluation of the site by the U.S. EPA.

IV. Promulgation of Part 201 Criteria for PFAS/PFOA.

The MDEQ recently announced that it has adopted regulations establishing drinking water criteria for perfluorooctanoic acid (PFOA) [CAS # 335-67-1] and perfluorooctanesulfonic acid (PFOS) [CAS # 1763-23-1] effective January 10, 2018. See 1/09/2018 DEQ Press Release, **Exhibit F**. The residential and nonresidential drinking water criteria are 0.07 µg/L (70 parts per trillion) for the combined concentrations of PFOA and PFOS. The timing of the rule promulgation is puzzling, as the PFOS/PFOA criteria were part of a proposed rules package that was reportedly subject to public comment through January 24, 2018 (which has since been extended to February 7, 2018). Yet, the rule in question was reportedly effective on January 10, 2018—fourteen days before the public comment period ended. Although we are encouraged that the MDEQ is working to establish Part 201 criteria for PFOS/PFOA contamination, we are concerned that the new rule has been published without a full opportunity for public comment and without a thorough consideration of all relevant factors.

According to the MDEQ press release, the PFOS/PFOA criteria of 0.07 µg/L for drinking water was established by reference to "health advisory values as presented in the United States Environmental Protection Agency Drinking Water Health Advisories for Perfluorooctanoic Acid (PFOA), EPA 822-R-16-005, May 2016 and Perfluorooctane Sulfonate (PFOS), EPA 822-R-16-004, May 2016." It is unclear why the DEQ did not use the algorithms in the Michigan Administrative Code Rule 299.10 or the toxicological or chemical-physical data of Rule 299.50, consistent with provisions of Rule 299.6, Rule 299.10(3), and Rule 299.34. We believe that additional consideration should be given to the target criteria for PFOS and PFOA, especially in light of the fact that other states have adopted more stringent criteria. For example, Vermont's limit for PFOS/PFOA is 20 parts per trillion and New Jersey's limit for PFOA is 14 parts per trillion and 13 parts per trillion for PFNA. Other states are considering regulation of additional types of PFAS as well.

Without further consideration of appropriate criteria for PFOS/PFOA and by short-circuiting the public-comment period, we are concerned that the newly adopted Part 201 drinking

water standard of 0.07 µg/L for drinking water may not be adequately protective for either short-term or chronic exposures.

V. Due Care Obligations

Part 201 imposes "due care" obligations on the owner/operator of a "facility" (such as the House Street Disposal Site or the Wolverine Tannery site). *See* MCL 324.20107a. Such due care obligations include a duty to undertake "response activity necessary to mitigate unacceptable exposure to hazardous substances." *See* MCL 324.20107a(1)(b). As you might expect, our clients are very concerned about the "due care" measures that will be implemented to mitigate unacceptable exposures to hazardous substances (including PFOS/PFOA and other hazardous substances emanating from the source area(s)).

The lack of transparency from Wolverine has prevented us from fully addressing all of Wolverine's due care obligations, but Wolverine is clearly not undertaking all appropriate due care obligations, as demonstrated by the following two examples:

- As explained above, all potentially impacted wells should be tested for all hazardous substances that may be present. Wolverine knows what was in its tannery waste. As confirmed by the testing, hazardous substances clearly exist at levels that could leach into groundwater. Due care necessarily includes residential well testing for these other substances.
- In certain investigation areas, Wolverine is refusing to provide water filters to households on the basis of a single "non-detect" water sample. This is true even where neighboring properties test positive for contaminants. As discussed above and in the AHC Technical Memorandum, contaminant levels in groundwater can fluctuate and the plume of contamination can move. Until adequate sampling has been performed to establish PFAS concentration levels over an extended period of time for each residential property, Wolverine should be required to provide water filtration systems to all homes that could even potentially be or become contaminated.

Furthermore, the House Street Disposal Site is a "facility" under Part 201. MCL 324.20114(1)(ii) imposes an obligation on liable parties who own a "facility" where contamination is present in excess of generic cleanup criteria (which is the case here) to provide notice to both the MDEQ and the owners of any property where hazardous substances are present within 30 days. *See* MCL 324.20114(1)(ii). Therefore, Wolverine has an obligation to provide the MDEQ and any owners of contamination where hazardous substances are present with the requisite notice.

Given Wolverine's "unconcerned" approach to environmental investigation and response activities to date, any enforcement efforts by the U.S. EPA and/or MDEQ should closely scrutinize all of Wolverine's due care obligations under Part 201 and CERCLA.

VI. Strict Monitoring Is Needed.

Wolverine's long history of disregard for the public's health demonstrates that strict monitoring of Wolverine's investigation and clean-up activities is absolutely necessary. Although many examples exist, a few are worth noting:

- In 1966, as a result of a lawsuit over Wolverine's use of the House Street Disposal Site, Wolverine was ordered (as a result of a settlement) to "see that water supplies and/or lakes or other waters not owned by the company will not be contaminated by any use made of said dump." See *Wolverine v. Twp. of Plainfield*, Kent Count Cir. Ct. No. 2609, May 6, 1966 Judgment at ¶ 2.A.(11)(emphasis added), **Exhibit G**. Wolverine's promise induced Plainfield Township and surrounding neighbors (who intervened in the lawsuit) to accept the settlement. Yet, despite the promise and despite the order existing to this day, it is clear Wolverine made no effort to comply with the order.
- In 1999, 3M (the manufacturer of "Scotchgard," which contained the PFAS used by Wolverine) had a meeting with Wolverine for the purpose of explaining the potential harmful effects of PFAS in 1999. See 1/15/1999 Letter from 3M, **Exhibit H**. 3M expressly told Wolverine that exposure could occur from the disposal of Scotchgard. Wolverine apparently did nothing in response.
- When Wolverine finally tested residential wells for PFAS in April 2017, Wolverine tested only a select few properties around the House Street Disposal Site *in a direction that Wolverine's consultant doubted the groundwater flows*. Even after those residential wells tested positive for PFAS, Wolverine did not recommend testing the residential wells in the direction that groundwater flows. Fortunately, a federally-required testing of a United States Armory to the south of the dump revealed the contamination in other directions.
- When news broke in 2017 about the contamination, Wolverine lied to the public, stating that Wolverine first heard about PFAS in its manufacturing process in Fall 2016. Wolverine got caught red-handed when 3M then released the January 15, 1999 letter. See 11/28/2017 letter from 3M, **Exhibit I**.
- As explained above, Wolverine attempted to remove waste from the MDOT Site and Imperial Pine without adequately analyzing it. Wolverine's actions demonstrate that it simply did not care what other substances may have been leaching into the groundwater. Fortunately, we insisted our consultant be there, whose samples and results provided the EPA's cited basis in its Administrative Order for authority under CERCLA. Again, had someone not scrutinized Wolverine's behaviors, Wolverine may have been able to disregard the alarming amount of hazardous substances at the House Street Disposal Site.

In the end, our clients are encouraged that the EPA and MDEQ have initiated enforcement actions against Wolverine, but are concerned that passive oversight will allow Wolverine to continually cut corners. Wolverine cannot be trusted to protect the interests of the public at large, as demonstrated by Wolverine's systemic failure to do so in the past. Stringent

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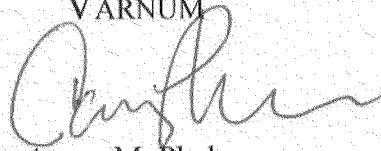
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enforcement by the EPA and MDEQ is necessary. We hope that both the EPA and MDEQ will consider our preliminary comments set forth in this letter.

Please feel free to contact me if we can be of any further assistance or if you would like to discuss any questions or comments you may have.

Very truly yours,

VARNUM

Aaron M. Phelps

AMP/sm
Enclosures

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Exhibit A

AMERICAN HYDROGEOLOGY CORPORATION

6869 S. Sprinkle Road · Portage, Michigan 49002
(269) 329-1600 · Fax (269) 329-2494
Email: service@americanhydrogeology.com

TECHNICAL MEMORANDUM

Date: January 22, 2018

To: Varnum LLP

From: Patrick Lynch, AHC

Re: Wolverine World Wide, Inc. Investigations

Introduction

The American Hydrogeology Corporation ("AHC") was retained to assist a large number of residential property owners for purposes of investigating and identifying appropriate removal and remedial actions taken by Wolverine World Wide, Inc. (Wolverine). The residential property owners have been impacted by contamination that is believed to be emanating from a former disposal area owned and operated by Wolverine (the "House Street Disposal Site"), along with several other suspected unlicensed disposal areas in the vicinity.

The following documents have been reviewed to assemble this initial critique of the preliminary plans and initial investigation procedures related to the above referenced matter: US EPA Unilateral Administrative Order for Removal Actions related to Wolverine Worldwide Tannery and House Street disposal site, GZA GeoEnvironmental (GZA) Conceptual Site Model and Remedial Investigation Work Plan for the former House Street disposal area dated November 27, 2017, and GZA Source Area Investigation Work Plan for Wolven Avenue area dated December 13, 2017. Comments are offered based on over thirty-seven (37) years of experience conducting systematic delineation of sites of environmental contamination. The primary purpose of our comments is to ensure systematic characterization of the source area(s) followed by diligent attention to tracking the fate and transport pathway for the complete assemblage of the contaminants of concern (COCs).

Notably, delineation projects of this type can be perceived to be more complex than they actually are due to investigators taking strokes that are too broad, thus losing track of preferential contaminant migration pathways that may be present. The ultimate goal and most beneficial outcome for all is to effectively and efficiently define the contaminant source and distribution.

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Failure to appropriately characterize the source area (including a consideration of the full assemblage of COCs) could significantly hamper subsequent investigations of the fate and transport of such COCs. A thorough understanding of the type and distribution of COCs within the source area(s) is necessary to design and implement an investigation plan to define or delineate the plume (or plumes) emanating from the source area. Delineation of contamination emanating from the source areas is necessary to identify all of the potential receptors affected by the COCs.

Source Area Characterization

The EPA order appropriately indicates that a thorough characterization of the source area(s) of all site(s) prior to initial remedial actions is necessary. Bypassing this crucial step could possibly lead to complications as the project proceeds and might also lead to inadvertent releases of contaminants that could escape the site(s) and move downgradient toward potential receptors. Moreover, failure to identify all COCs within the source area might result in a corresponding failure to conduct adequate sampling and/or monitoring activities to address such COCs.

AHC anticipates that it may have additional comments based on work plans submitted to the EPA pursuant to the EPA Order.

Conceptual Site Model (CSM)

In its CSM, GZA has modeled the regional geology and hydrogeology of the House Street Disposal area using statewide GIS data, existing regional geological maps, and water well logs. Although AHC realizes that this data likely constitutes most of the currently available information, AHC cautions that the data sources themselves are very generalized and, in some cases, unreliable. The issues with these resources will be discussed below.

The statewide surficial geological map is highly generalized and outdated. This map has been shown to be inaccurate with respect to surficial materials when used for small areas or specific sites. There is actually a more recent surficial geological map for Kent County that was not referenced in the CSM.

The statewide GIS data used for estimating hydraulic conductivity and transmissivity are based on interpolation of often inaccurately located water well log lithologies, which are known to be unreliable in many cases. This creates significant uncertainty when interpolating unreliable data into areas where no data is present. The complex glacial stratigraphy in this part of Michigan makes this problem particularly significant.

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It must be kept in mind that the use of water well log lithologies to estimate hydraulic conductivities is based on the interpretations of water well drillers, who are not geologists or engineers and in some cases use outdated or anecdotal terms for geological materials (i.e. hardpan), which vary from driller to driller. Although some water well drillers make high quality logs, others are highly inaccurate. The dilemma for anyone attempting to use these logs is to determine which is which.

The re-interpretation of the hundreds of terms used on water well logs into four units (AQ, MAQ, PCM, and CM) adds another level of uncertainty. The estimates of groundwater flow velocity used in the CSM are based on a geometric mean of values assigned to these re-interpreted water well lithologies in a complete log, adding yet another level of uncertainty. It is most likely that contaminant movement will occur through layers of sediment with higher relative hydraulic conductivity rather than through the entire sequence of materials and that the groundwater flow velocity in these layers will be higher than the average.

The problems with water well logs are known to every geologist who tries to use this data. One specific problem is that many of the wells in the Wellog database are not correctly located. Locations of these wells must be validated before using them in geological models and cross sections. While water well logs constitute the only types of data available in many places, they cannot be considered to be an accurate representation of the subsurface geology.

In summary, while the CSM may be based on the best information available at this time, a site specific hydrogeologic investigation properly conducted should produce the data needed to delineate the source area(s) of each site of contamination. The EPA and MDEQ should require a thorough hydrogeologic investigation.

Remedial Investigation Work Plan(s)

The work plans proposed by GZA are adequate in many aspects, although AHC notes a number of deficiencies (based upon decades of investigating the glacial stratigraphy and hydrogeology of Michigan).

First, the procedure for logging boreholes for characterization and monitor well installation omits a critical form of data -- the gamma ray log. When correlating glacial units in a more regional project, gamma ray logs are in most cases more useful than sediment descriptions, because of patterns that can be correlated from borehole to borehole. The cost of obtaining these logs is relatively low compared to the overall cost of drilling. Gamma ray logging should be an essential component of the work plans.

Second, the Unified Soil Classification System will be used for sediment classification. This system is adequate for most types of unconsolidated materials, but in glaciated areas (such as the area at issue here), additional information is highly useful. For example, knowing that a sample is a diamicton or till, a property easily recognizable to the geologist logging the hole, is very important in addition to the USCS classification of CL. Describing these types of characteristics will make correlation of the boreholes much easier.

Third, vertical profiling is a critical part of plume delineation. This task is currently proposed to be accomplished by sampling every 20 feet during drilling using 10-foot temporary screens. AHC's experience with contaminant plumes confirms that 20-foot intervals are too large, thus increasing the chance of missing thin zones of transport. In addition, the 10-foot screen length can lead to significant dilution of contaminants that may be moving in these thin beds of coarser material. AHC recommends that profiling should be done at 10-foot intervals and that 5-foot screens be used. Similarly, 5-foot screens for the monitor wells installed based on vertical profiling will better reflect the true concentrations of the COCs. AHC also recommends that vertical profiling and gamma logging be done at plume boundaries as well as along the estimated centerline of the plume. Absent modifications of the work plans to address these concerns, the current vertical profiling plan could both miss zones of transport and not reflect the true concentrations of the COCs.

Fourth, of the too-few wells sampled more than once, significant variation in some of the PFOS and PFOA values in domestic water well samples were reported in the GZA Conceptual Site Model and Remedial Investigation Work Plan. Sample results on GZAs table that appear to be from untreated wells show a variation of concentrations on different sample dates. For example "PARCEL Number 17" varied between 27,600 ng/L on 7/18/17 and 37,800 ng/L on 8/16/17, and "PARCEL Number 18" was 1,430 ng/L on 7/20/17 and 2,220 ng/L on 9/20/17. Additionally, a sample from "PARCEL Number 3" was 0.0 ng/L on 4/19/17 and then when the well was resampled on 6/12/17 it was 9.8 ng/L. Other locations show variation between monthly samples. These results raise the possibility that a non-detect or low value from a well might not reflect the true variation in concentration. Furthermore, seasonal and broader climatic patterns which affect groundwater infiltration rates, groundwater levels, and flow velocity are well known to cause fluctuation in contaminant concentrations. AHC therefore recommends that domestic wells be

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re-sampled periodically to confirm these results including any domestic wells with an initial non-detect value.¹

Last, based on the uncertainties of water well log data, as described above, the remedial investigation work plans should clearly state that groundwater potentials and flow directions will be continually refined as new wells are installed to more accurately characterize the groundwater flow system as the plume delineation progresses.

In summary, detailed systematic delineation of the COCs at each site is imperative. GZA's work plans should be revised to address the deficiencies noted above.

¹ This is especially true because of Wolverine's current plans for providing alternative water or water filters. Some homes with an initial non-detect are not getting a water-filtration system from Wolverine (even if a neighbor has a positive test). In addition, Wolverine's maintenance plan for the water filters depends on the level of contaminants in the initial test.

Exhibit B

Results expressed in $\mu\text{g}/\text{Kg}$ dry weight.

Data Qualifiers:	
J	Estimated value

U Not detected
UJ Not detected. Quantitation limit may be inaccurate or imprecise.

Footnotes/Abbreviations:

¹⁴⁾ Part 201 Residential Soil Generic Cleanup Criteria and Screening Levels

¹²³ MDEQ Media Specific Volatilization to Indoor Air Interim Action Set

^(c) Bolded non-detect value exceeds background level and an applicable time-sensitive screening level in any media will warrant expedited

(b) Background, as defined in 292.501(b), may be substituted for the chemical-specific background.

(c) Value is screening level based on the chemical-specific generic background.

(d) Value is screening level based on the chemical-specific generic background, as defined in 292.501(b), may be substituted for the chemical-specific background.

(e) Criterion dependent on receiving surface water hardness; calcium hardness.

(H) Where data are provided for total chromium only; samples and

(M) Calculated criterion is below the target detection limit (TDL);

(W) Concentrations of trihalomethanes must be added together to

(x) Criterion is not protective for surface water used as a drinking groundwater surface water interface protection

NA	not available
RBST	risk based screening level

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Exhibit C

Table 1 - Waste/Soil Data Summary

Wolverine Worldwide Dump Site on Imperial Pine Drive

October 2017

Sample Location: Investigative/Field Duplicate/QC:		SS-04 Investigative	SS-05 Investigative	Statewide Default Background Levels ⁽¹⁾	Drinking Water Protection Criteria & RBSLs ⁽¹⁾	GSIP Criteria & RBSLs ⁽¹⁾	Particulate Soil Inhalation Criteria & RBSLs ⁽¹⁾	Direct Contact Criteria & RBSLs ⁽¹⁾	Proposed VI Tier I SL ⁽²⁾
Laboratory ID:		463879001	463879002						
Collection Date:		10/25/17	10/25/17						
Metals, Total	CAS Number								
Arsenic (B)	7440-38-2	3,320	3,190	5,800	4,600	4,600	7.20E+05	7,600	NA
Barium (B)	7440-39-3	61,000	39,400	75,000	1.30E+06	4.40E+05 (G)	3.30E+08	3.70E+07	NA
Cadmium (B)	7440-43-9	1,010	373	1,200	6,000	3,600 (G,X)	1.70E+06	5.50E+05	NA
Chromium, Hexavalent	18540-29-9	2,730,000	65,800 U	18,000 (total)	30,000	3,300	2.60E+05	2.50E+06	NA
Chromium, Total (B)	7440-47-3	19,500,000	1,010,000	18,000 (total)	—	—	—	—	—
Chromium, Trivalent - Calculated (B)	16065-83-1	16,770,000	1,010,000	18,000 (total)	1.00E+09	2.90E+09 (G,X)	3.30E+08	7.90E+08	NA
Copper (B)	7440-50-8	27,800	22,500	32,000	5.80E+06	75,000 (G)	1.30E+08	2.00E+07	NA
Lead (B)	7439-92-1	21,800,000	337,000	21,000	7.00E+05	5.10E+06 (G,X)	1.00E+08	4.00E+05	NA
Mercury (Total) (B)	7439-97-6	40.8 J	61.7 J	130	1,700	50 (M); 1.2	2.00E+07	1.60E+05	0.027
Selenium (B)	7782-49-2	212 J	341	410	4,000	400	1.30E+08	2.60E+06	NA
Silver (B)	7440-22-4	69.3 J	38.7 J	1,000	4,500	100 (M); 27	6.70E+06	2.50E+06	NA
Zinc (B)	7440-66-6	294,000	56,200	47,000	2.40E+06	1.70E+05 (G)	ID	1.70E+08	NA
Solids, Total (%)	—	45.9	68.3	—	—	—	—	—	—

Results expressed in µg/Kg dry weight.

Bolded values exceed background levels and an applicable criterion.

Data Qualifiers:

J Estimated value

U Not detected

Footnotes/Abbreviations:

⁽¹⁾Part 201 Residential Soil Generic Cleanup Criteria and Screening Levels/Part 213 Risk-based Screening Levels, December 30, 2013.⁽²⁾Proposed VI Tier 1 Groundwater, Soil and Vapor Screening Levels, Part 201 Generic Screening Levels/Part 213 Risk-based Screening Levels, August, 29, 2017.

(B) Background, as defined in R 299.5701(b), may be substituted if higher than the calculated criterion.

(G) Criterion dependent on receiving surface water hardness; calculated criteria based on water hardness of 150 mg/L.

(M) Calculated criterion is below the target detection limit (TDL); first number is the criterion (TDL), the second is the risk-based value.

(X) Criterion is not protective for surface water used as a drinking water source.

GSIP groundwater surface water interface protection

ID Insufficient data to develop criterion.

NA not available

RBSL risk based screening level

SL screening level

VI vapor intrusion



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12/21/2017

Exhibit D

Table XX - Groundwater Data Summary
Residential Drinking Water Well Analyses Near the House Street Dump Site

January 2018

Monitoring Location:		1781 House St.	1850 House St.	7425 Chandler	7885 Imperial Pine	Federal MCL ⁽¹⁾	Residential DWC ⁽²⁾
Laboratory ID:		465779002	465779003	465779004	465779001		
Collection Date:		12/11/17	12/11/17	12/11/17	12/11/17		
Pesticides	CAS Number						
Alkalinity, Bicarbonate (CaCO ₃)	NA	380,000	499,000	301,000	305,000	--	--
Alkalinity, Total as CaCO ₃	NA	380,000	499,000	301,000	305,000	--	--
Chloride	16887-00-6	40,000	88,600	60,800	124,000	2.50E+05 (SMCL)	2.50E+05 (E)
Hardness, Total	NA	379,000	526,000	310,000	430,000	--	--
Solids, Total Dissolved	NA	506,000	878,000	548,000	616,000	5.00E+05 (SMCL)	5.00E+05 (E)
Sulfate	14808-79-8	23,400	114,000	28,700	29,300	2.50E+05 (SMCL)	2.50E+05 (E)
Metals, Total	CAS Number						
Arsenic (B)	7440-38-2	5 U	5 U	5 U	5 U	10	10
Barium (B)	7440-39-3	100 U	500 U	100 U	100 U	2,000	2,000
Cadmium (B)	7440-43-9	1 U	1 U	1 U	1 U	5.0	5.0
Calcium	7440-70-2	92,200	134,000	83,700	98,900	--	--
Chromium, Total (B, H)	7440-47-3	10 U	10 U	10 U	10 U	100	100
Chromium, Hexavalent	18540-29-9	10 U	10 U	10 U	10 U	--	100
Chromium, Trivalent - Calculated (B, H)	16065-83-1	10 U	10 U	10 U	10 U	--	100
Copper (B)	7440-50-8	43.8	31.7	18.2	17.5	1,300 (AL)	1,000 (E)
Iron (B)	7439-89-6	71.8	10 U	48.1	10 U	300	300 (E)
Lead (B)	7439-92-1	3 U	22.5	3 U	3 U	15 (AL)	4.0 (L)
Magnesium (B)	7439-95-4	36,100	46,700	24,600	44,400	--	4.00E+05
Mercury (B)	7439-97-6	0.2 U	0.2 U	0.2 U	0.2 U	2.0	2.0
Selenium (B)	7782-49-2	5 U	5 U	5 U	5 U	50	50
Silver (B)	7440-22-4	0.2 U	0.2 U	0.2 U	0.2 U	100 (SMCL)	34
Sodium	17341-25-2	38,100	108,000	31,800	44,500	--	2.30E+05
Zinc (B)	7440-66-6	50 U	89.4	54.8	50 U	5,000 (SMCL)	2,400

Results expressed in µg/L.

Bolded values exceed an applicable criterion.

Data Qualifiers:

U Not detected

Footnotes/Abbreviations:

⁽¹⁾ National Primary Drinking Water Regulations, US EPA 816-F-09-004, May 2009.⁽²⁾ Part 201 Groundwater Generic Cleanup Criteria/Part 213 Tier 1 Risk-based Screening Levels, December 30, 2013.

(B) Background, as defined in R 299.5701(b), may be substituted if higher than the calculated criterion.

(E) Aesthetic drinking water value. Notice of aesthetic impact may be employed as an institutional control if concentration exceeds the aesthetic DWC but not the health-based DW value.

(H) Data provided for total Chromium only; compare to hexavalent Chromium criteria.

(L) Concentrations up to the State action level of 15 µg/L may still allow for drinking water use if soil concentrations are below 400 mg/Kg.

(AL) action level

(SMCL) secondary maximum contaminant level

DWC drinking water criterion

MCL maximum contaminant level

NA not available



1/19/2018

C:\Users\sjmurray\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.Outlook\K0P5XYR\TBLXX_GW-DataSummary_2018_0102.xlsx

EPA-R5-2018-007926_0000042

Exhibit E



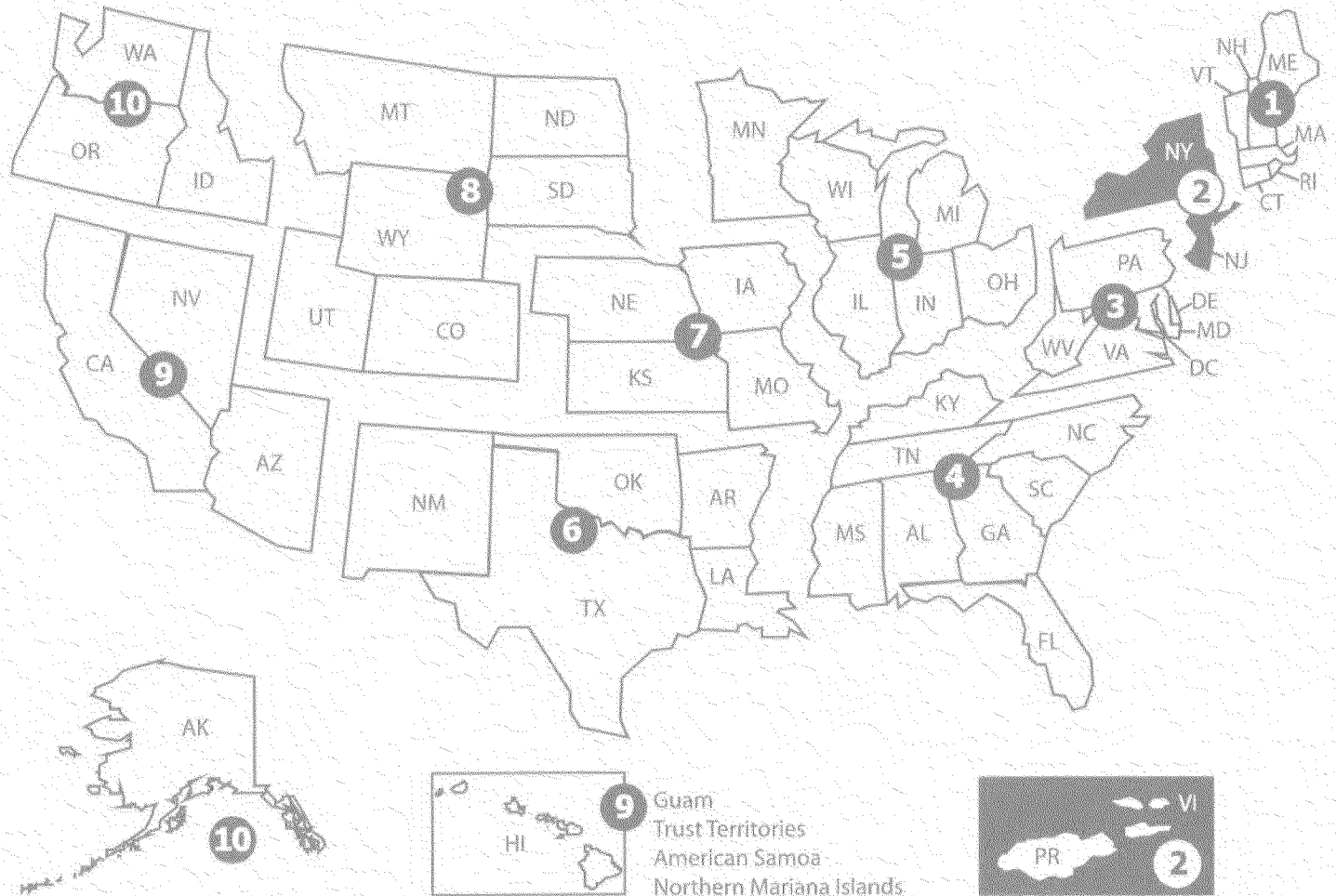
United States
Environmental Protection
Agency

1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

July 2017

Office of Land and Emergency Management

Support Document for the Revised National Priorities List Final Rule – Saint-Gobain Performance Plastics



**Support Document for the
Revised National Priorities List
Final Rule
Saint-Gobain Performance Plastics
July 2017**

**Site Assessment and Remedy Decisions Branch
Office of Superfund Remediation and Technology Innovation
Office of Land and Emergency Management
U.S. Environmental Protection Agency
Washington, DC 20460**

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 Appendix A: May 2016, EPA Response to External Peer Review Comments on EPA Draft Documents: Health Effects Support Document for Perfluorooctanoic Acid (PFOA) and Health Effects Support Document for Perfluorooctane Sulfonate (PFOS). (99 pages)		
 Appendix B: January 3, 2017 Teleconference Note: Conversation with Jim Hurlburt, Hoosick Falls Water Department, Subject: Village Well 6. (1 page)		

Executive Summary

Section 105(a)(8)(B) of CERCLA, as amended by SARA, requires that the EPA prepare a list of national priorities among the known releases or threatened releases of hazardous substances, pollutants, or contaminants throughout the United States. An original National Priorities List (NPL) was promulgated on September 8, 1983 (48 FR 40658). CERCLA requires that EPA update the list at least annually.

This document provides responses to public comments received on the Saint-Gobain Performance Plastics site, proposed on September 9, 2016 (81 FR 62428). This site is being added to the NPL based on an evaluation under EPA's Hazard Ranking System (HRS) in a final rule published in the *Federal Register* in July 2017.

Introduction

This document explains the rationale for adding the Saint-Gobain Performance Plastics site in Village of Hoosick Falls, New York to the National Priorities List (NPL) of uncontrolled hazardous waste sites and provides responses to public comments received on this site listing proposal. The EPA proposed this site to the NPL on September 9, 2016 (81 FR 62428). This site is being added to the NPL based on an evaluation under the Hazard Ranking System (HRS) in a final rule published in the *Federal Register* in July 2017.

Background of the NPL

In 1980, Congress enacted the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), 42 U.S.C. Sections 9601 *et seq.* in response to the dangers of uncontrolled hazardous waste sites. CERCLA was amended on October 17, 1986, by the Superfund Amendments and Reauthorization Act (SARA), Public Law No. 99-499, stat., 1613 *et seq.* To implement CERCLA, EPA promulgated the revised National Oil and Hazardous Substances Pollution Contingency Plan (NCP), 40 CFR Part 300, on July 16, 1982 (47 FR 31180), pursuant to CERCLA Section 105 and Executive Order 12316 (46 FR 42237, August 20, 1981). The NCP, further revised by EPA on September 16, 1985 (50 FR 37624) and November 20, 1985 (50 FR 47912), sets forth guidelines and procedures needed to respond under CERCLA to releases and threatened releases of hazardous substances, pollutants, or contaminants. On March 8, 1990 (55 FR 8666), EPA further revised the NCP in response to SARA.

Section 105(a)(8)(A) of CERCLA, as amended by SARA, requires that the NCP include

criteria for determining priorities among releases or threatened releases throughout the United States for the purpose of taking remedial action and, to the extent practicable, take into account the potential urgency of such action, for the purpose of taking removal action.

Removal action involves cleanup or other actions that are taken in response to emergency conditions or on a short-term or temporary basis (CERCLA Section 101). Remedial action is generally long-term in nature and involves response actions that are consistent with a permanent remedy for a release (CERCLA Section 101). Criteria for placing sites on the NPL, which makes them eligible for remedial actions financed by the Trust Fund established under CERCLA, were included in the HRS. EPA promulgated the HRS as Appendix A of the NCP (47 FR 31219, July 16, 1982). On December 14, 1990 (56 FR 51532), EPA promulgated revisions to the HRS in response to SARA, and established the effective date for the HRS revisions as March 15, 1991.

Section 105(a)(8)(B) of CERCLA, as amended, requires that the statutory criteria provided by the HRS be used to prepare a list of national priorities among the known releases or threatened releases of hazardous substances, pollutants, or contaminants throughout the United States. The list, which is Appendix B of the NCP, is the NPL.

An original NPL of 406 sites was promulgated on September 8, 1983 (48 FR 40658). At that time, an HRS score of 28.5 was established as the cutoff for listing because it yielded an initial NPL of at least 400 sites, as suggested by CERCLA. The NPL has been expanded several times since then, most recently on September 9, 2016 (81 FR 62397). The Agency also has published a number of proposed rulemakings to add sites to the NPL. The most recent proposal was on September 9, 2016 (81 FR 62428).

Development of the NPL

The primary purpose of the NPL is stated in the legislative history of CERCLA (Report of the Committee on Environment and Public Works, Senate Report No. 96-848, 96th Cong., 2d Sess. 60 [1980]).

The priority list serves primarily informational purposes, identifying for the States and the public those facilities and sites or other releases which appear to warrant remedial actions. Inclusion of a facility or site on the list does not in itself reflect a judgment of the activities of its owner or operator, it does not require those persons to undertake any action, nor does it assign liability to any person. Subsequent government actions will be necessary in order to do so, and these actions will be attended by all appropriate procedural safeguards.

The NPL, therefore, is primarily an informational and management tool. The identification of a site for the NPL is intended primarily to guide EPA in determining which sites warrant further investigation to assess the nature and extent of the human health and environmental risks associated with the site and to determine what CERCLA-financed remedial action(s), if any, may be appropriate. The NPL also serves to notify the public of sites EPA believes warrant further investigation. Finally, listing a site may, to the extent potentially responsible parties are identifiable at the time of listing, serve as notice to such parties that the Agency may initiate CERCLA-financed remedial action.

CERCLA Section 105(a)(8)(B) directs EPA to list priority sites among the known releases or threatened release of hazardous substances, pollutants, or contaminants, and Section 105(a)(8)(A) directs EPA to consider certain enumerated and other appropriate factors in doing so. Thus, as a matter of policy, EPA has the discretion not to use CERCLA to respond to certain types of releases. Where other authorities exist, placing sites on the NPL for possible remedial action under CERCLA may not be appropriate. Therefore, EPA has chosen not to place certain types of sites on the NPL even though CERCLA does not exclude such action. If, however, the Agency later determines that sites not listed as a matter of policy are not being properly responded to, the Agency may consider placing them on the NPL.

Hazard Ranking System

The HRS is the principle mechanism EPA uses to place uncontrolled waste sites on the NPL. It is a numerically based screening system that uses information from initial, limited investigations -- the preliminary assessment and site inspection -- to assess the relative potential of sites to pose a threat to human health or the environment. HRS scores, however, do not determine the sequence in which EPA funds remedial response actions, because the information collected to develop HRS scores is not sufficient in itself to determine either the extent of contamination or the appropriate response for a particular site. Moreover, the sites with the highest scores do not necessarily come to the Agency's attention first, so that addressing sites strictly on the basis of ranking would in some cases require stopping work at sites where it was already underway. Thus, EPA relies on further, more detailed studies in the remedial investigation/feasibility study that typically follows listing.

The HRS uses a structured value analysis approach to scoring sites. This approach assigns numerical values to factors that relate to or indicate risk, based on conditions at the site. The factors are grouped into three categories. Each category has a maximum value. The categories are:

- likelihood that a site has released or has the potential to release hazardous substances into the environment;
- characteristics of the waste (e.g., toxicity and waste quantity); and
- targets (e.g., people or sensitive environments) affected by the release.

Under the HRS, four pathways can be scored for one or more components and threats as identified below:

- Ground Water Migration (S_{gw})

- Surface Water Migration (S_{sw})
The following threats are evaluated for two separate migration components, overland/flood migration and ground water to surface water.
 - drinking water
 - human food chain
 - sensitive environments
- Soil Exposure (S_s)
 - resident population
 - nearby population
- Air Migration (S_a)
 - population

After scores are calculated for one or more pathways according to prescribed guidelines, they are combined using the following root-mean-square equation to determine the overall site score (S), which ranges from 0 to 100:

$$S = \sqrt{\frac{S_{gw}^2 + S_{sw}^2 + S_s^2 + S_a^2}{4}}$$

If all pathway scores are low, the HRS score is low. However, the HRS score can be relatively high even if only one pathway score is high. This is an important requirement for HRS scoring because some extremely dangerous sites pose threats through only one pathway. For example, buried leaking drums of hazardous substances can contaminate drinking water wells, but -- if the drums are buried deep enough and the substances not very volatile -- not surface water or air.

Other Mechanisms for Listing

There are two mechanisms other than the HRS by which sites can be placed on the NPL. The first of these mechanisms, authorized by the NCP at 40 CFR 300.425(c)(2), allows each State and Territory to designate one site as its highest priority regardless of score. The last mechanism, authorized by the NCP at 40 CFR 300.425(c)(3), allows listing a site if it meets the following three requirements:

- Agency for Toxic Substances and Disease Registry (ATSDR) of the U.S. Public Health Service has issued a health advisory that recommends dissociation of individuals from the release;
- EPA determines the site poses a significant threat to public health; and
- EPA anticipates it will be more cost-effective to use its remedial authority than to use its emergency removal authority to respond to the site.

Organization of this Document

The following section contains EPA responses to site-specific public comments received on the proposal of the Saint-Gobain Performance Plastics site on September 9, 2016 (81 FR 62428). The site discussion begins with a list of commenters, followed by a site description, a summary of comments, and Agency responses to each comment. A concluding statement indicates the effect of the comments on the HRS score for the site.

Glossary

The following acronyms and abbreviations are used throughout the text:

Agency	U.S. Environmental Protection Agency
ATSDR	Agency for Toxic Substances and Disease Registry
BMC	Benchmark concentration
BMD	Benchmark dose
BMDL	Benchmark dose limit
BMR	Benchmark response
CAR	Constitutive androstane receptor
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act of 1980, 42 U.S.C. Sections 9601 <i>et seq.</i> , also known as Superfund
CFR	Code of Federal Regulations
cis-1,2-DCE	cis-1, 2-dichloroethene
CLP	EPA Contract Laboratory Program
CRQL	Contract-required quantitation limit
DL	Detection limit
EPA	U.S. Environmental Protection Agency
ESA	Environmental site assessment
FR	Federal Register
FXR	Farnesoid receptor
GD	Gestational day
GAC	Granular activated carbon
HED	Human equivalent dose
HRS	Hazard Ranking System, Appendix A of the NCP
HRS score	Overall site score calculated using the Hazard Ranking System; ranges from 0 to 100
HWQ	Hazardous waste quantity
LOAEL	Lowest observed adverse effect level
MCL	Maximum contaminant level
MDL	Method detection limit
µg/kg	Microgram per kilogram
µg/L	Microgram per liter
mg/kg/day	Milligram per kilogram per day
MW	Monitoring well
MWS	Municipal water supply

NCP	National Oil and Hazardous Substances Pollution Contingency Plan, 40 C.F.R. Part 300
ng/L	Nanograms per liter
NOAEL	No observed adverse effect level
NPL	National Priorities List, Appendix B of the NCP
NYDEC	New York State Department of Environmental Conservation
PCB	Polychlorinated biphenyl
PFAA	Perfluoroalkyl acid
PFOA	Perfluorooctanoic acid
PFOS	Perfluorooctane sulfonate
PK	Pharmacokinetic
POD	Point of departure
PPARα	Peroxisome proliferator-activated receptor
PPB	Parts per billion
PPM	Parts per million
PPT	Parts per trillion
PRP	Potentially responsible party
PSW	Public supply well
PXR	Pregnane X receptor
RDL	Reporting detection limit
RfD	Reference dose
RI	Remedial investigation
RI/FS	Remedial Investigation/feasibility study
SARA	Superfund Amendments and Reauthorization Act
SCDM	Superfund Chemical Data Matrix
SGPP	Saint-Gobain Performance Plastics
SOW	Statement of work
SQL	Sample quantitation limit
TAL	Target analyte list
TCE	Trichloroethylene
TSCA	Toxic Substances Control Act
UF	Uncertainty factor
VC	Vinyl chloride
Vd	Volume of distribution
VOC	Volatile organic compounds

1. List of Commenters and Correspondence

EPA-HQ-OLEM-2016-0434-0004	Correspondence, undated, from Basil Seggos, Acting Commissioner, Office of the Commissioner, New York State Department of Environmental Conservation.
EPA-HQ-OLEM-2016-0434-0005	Comment, dated September 20, 2016, submitted by Kathy Marchione, State Senator, 43rd District, State of New York.
EPA-HQ-OLEM-2016-0434-0006	Comment, submitted by Anonymous Commenter.
EPA-HQ-OLEM-2016-0434-0007	Correspondence, dated January 14, 2016, from Basil Seggos, Acting Commissioner, Office of the Commissioner, New York State Department of Environmental Conservation.
EPA-HQ-OLEM-2016-0434-0008	Comment, dated November 4, 2016, submitted by Stan Brownell, Chairman, and Lester Goodermote, Legislator, Office of the Majority, Rensselaer County Legislature, New York.
EPA-HQ-OLEM-2016-0434-0009	Comment, dated November 6, 2016, submitted by David B. Borge, Mayor, Village of Hoosick Falls, New York.
EPA-HQ-OLEM-2016-0434-0010	Comment, submitted by James Donovan, Hoosick Falls, New York.
EPA-HQ-OLEM-2016-0434-0011	Comment, submitted by Anonymous Commenter, Hoosick Falls, New York.
EPA-HQ-OLEM-2016-0434-0012	Comment, submitted by Anonymous Commenter, Hoosick Falls, New York.
EPA-HQ-OLEM-2016-0434-0013	Comment, dated September 25, 2016, submitted by John Bozeman, Lackland, Texas.
EPA-HQ-OLEM-2016-0434-0014	Correspondence, undated, from Terry Jeng, Office of Superfund Remediation and Technology Innovation, USEPA.
EPA-HQ-OLEM-2016-0434-0015	Comment, dated November 8, 2016, submitted by Christopher R. Gibson, Archer Attorneys at Law, on behalf of Saint-Gobain Performance Plastics Corporation.

2. Site Description

The Saint-Gobain Performance Plastics (SGPP) site for HRS scoring purposes consists of soil and ground water contaminated with trichloroethylene (TCE), cis-1, 2-dichloroethene (cis-1, 2-DCE), vinyl chloride, polychlorinated biphenyls (PCBs), and perfluorooctanoic acid (PFOA) as a result of the historical release from activities at the SGPP facility located at 14 McCaffrey Street in the Village of Hoosick Falls, NY. The EPA sampling conducted in April–May 2016 document the presence of TCE, cis-1,2-DCE, PCBs and PFOA in facility soils, and TCE, vinyl chloride and PFOA in ground water (See Figure 1, Site Location Map and Figure 2, Sample Results Map, of this support document). Sampling and analysis by the EPA of the Village of Hoosick Falls municipal water supply in May 2016 document contamination of vinyl chloride above the cancer risk screening concentration in the Village of Hoosick Falls drinking water well number 6. The Village of Hoosick Falls drinking water wells were also found to be contaminated with PFOA (in Village wells 3 and 7). In addition, information provided by SGPP to the EPA in December 2014 documents an observed release by direct observation of PFOA to the aquifer of concern.

Chlorinated solvents such as TCE are associated with historical manufacturing activities performed at the SGPP facility. Cis-1, 2-DCE and vinyl chloride are degradation products of TCE. Manufacturing processes at the facility included the use of certain non-stick coatings, the manufacture of a variety of polymer-based products including high-performance polymeric films and membranes as well as foams for bonding and sealing. Fluoropolymers used to manufacture non-stick coatings are known to include PFOA.

The Village of Hoosick Falls obtains its drinking water from three public supply wells, each of which is evaluated in the HRS package for the SGPP site (PSW 3, 6, and 7). The wells draw water from the lower portion of the sand and gravel aquifer underlying the Village of Hoosick Falls and the Hoosic River. The areal extent of the sand and gravel aquifer is generally limited to the Hoosic River valley. This lower portion of the aquifer is overlain by approximately 8 feet of poorly permeable clay and silt under much of the Village and at the facility, but the thickness of this layer varies considerably. This clay and silt layer can be a local barrier to downward water flow and separates the lower portion of the sand and gravel aquifer from the shallow portion of the sand and gravel aquifer, which overlays the clay and silt layer in areas where the clay layer is present. However, because the lower aquifer exhibits “leaky artesian conditions” and there is evidence of site-attributable hazardous substance migration across the silt and clay layer, the upper and lower portions of the aquifer are evaluated together as a single hydrologic unit (discussed further in section 3.9.2, Observed Releases – Attribution, of this support document). Although the pre-well development ground water flow direction in the vicinity of the SGPP facility and the Village of Hoosick Falls wells was likely northward in the direction of flow of the Hoosic River, the pumping of the village wells has created a radius of influence (i.e., causes flow gradients to be toward the wells) that extends out as far as 0.67 mile and encompasses the SGPP facility. Shallow ground water flow beneath the SGPP facility is northwest to southeast toward the Village of Hoosick Falls wells.

The Village of Hoosick Falls public well system presently serves a population of approximately 4,000 people based on information obtained from the Hoosick Falls Water Department.

Figure 1: Site Location Map



Notes:

1. SGP-113 was collected from the sewage system pit located within the facility building.
2. The analyte was analytically identified; the associated numerical value is the approximate concentration in the sample.

Legend:

- Groundwater Sample Location
- Waste Water Sample Location
- Soil Boring Location

SGP-113
SGP-113A
SGP-113B
SGP-113C

SGP-112
SGP-112A
SGP-112B
SGP-112C

SGP-111
SGP-111A
SGP-111B
SGP-111C

SGP-110
SGP-110A
SGP-110B
SGP-110C

SGP-109
SGP-109A
SGP-109B
SGP-109C

SGP-108
SGP-108A
SGP-108B
SGP-108C

SGP-107
SGP-107A
SGP-107B
SGP-107C

SGP-106
SGP-106A
SGP-106B
SGP-106C

SGP-105
SGP-105A
SGP-105B
SGP-105C

SGP-104
SGP-104A
SGP-104B
SGP-104C

SGP-103
SGP-103A
SGP-103B
SGP-103C

SGP-102
SGP-102A
SGP-102B
SGP-102C

SGP-101
SGP-101A
SGP-101B
SGP-101C

SGP-100
SGP-100A
SGP-100B
SGP-100C

SGP-99
SGP-99A
SGP-99B
SGP-99C

SGP-98
SGP-98A
SGP-98B
SGP-98C

SGP-97
SGP-97A
SGP-97B
SGP-97C

SGP-96
SGP-96A
SGP-96B
SGP-96C

SGP-95
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SGP-95B
SGP-95C

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SGP-94B
SGP-94C

SGP-93
SGP-93A
SGP-93B
SGP-93C

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SGP-92B
SGP-92C

SGP-91
SGP-91A
SGP-91B
SGP-91C

SGP-90
SGP-90A
SGP-90B
SGP-90C

SGP-89
SGP-89A
SGP-89B
SGP-89C

SGP-88
SGP-88A
SGP-88B
SGP-88C

SGP-87
SGP-87A
SGP-87B
SGP-87C

SGP-86
SGP-86A
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SGP-86C

SGP-85
SGP-85A
SGP-85B
SGP-85C

SGP-84
SGP-84A
SGP-84B
SGP-84C

SGP-83
SGP-83A
SGP-83B
SGP-83C

SGP-82
SGP-82A
SGP-82B
SGP-82C

SGP-81
SGP-81A
SGP-81B
SGP-81C

SGP-80
SGP-80A
SGP-80B
SGP-80C

SGP-79
SGP-79A
SGP-79B
SGP-79C

SGP-78
SGP-78A
SGP-78B
SGP-78C

SGP-77
SGP-77A
SGP-77B
SGP-77C

SGP-76
SGP-76A
SGP-76B
SGP-76C

SGP-75
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SGP-75B
SGP-75C

SGP-74
SGP-74A
SGP-74B
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3. Summary of Comments

Commenters both supported and questioned the proposed addition of the Saint-Gobain Performance Plastics site to the NPL. The supporting commenters included the State of New York, a State Government representative, the Mayor of the Village of Hoosick Falls, two Rensselaer County Legislators, residents of the Village of Hoosick Falls and other individuals.

Acting Commissioner, Basil Seggos of the Office of the Commissioner, New York State Department of Environmental Conservation, requested that the Saint-Gobain Performance Plastics site be included on the NPL after the EPA conducts an investigation. He indicated that he looks forward to continuing collaboration at all levels of the government to address the PFOA contamination and ensuring no additional hardship on Village residents.

Nine commenters, which included State Senator Kathy Marchione, 43rd District, New York; Stan Brownell and Lester Goodermote of the Rensselaer County Legislature, New York; Mayor David B. Borge, Village of Hoosick Falls, New York; three anonymous commenters; two Hoosick Falls residents; and 1 additional public commenter, John Bozeman of Lackland, Texas, supported listing the Site on the NPL. They expressed concerns for public health, remediation, impact on property values, other pollution in Hoosick Falls, collaboration with the New York State Department of Environmental Conservation, and Superfund resources to address the Site.

Commenters, while not opposing the placement of the Site on the NPL, included individuals concerned with the impact of the listing on the community. Mr. Brownell and Mr. Goodermote of the Rensselaer County Legislature, New York, stated that the discovery of PFOAs has affected the image of the Village and has possibly impacted property values, but an effective remediation effort can do a great deal to restore the standing of the Village and address the reasonable concerns regarding health and safety. An anonymous commenter indicated that his/her home is not worth anything.

Saint-Gobain Performance Plastics Corporation opposed listing the Site on the NPL and questioned the need for the listing as they asserted that the contamination from their facility is already being addressed in an agreement with the State. SGPP also commented that the EPA made multiple errors in its HRS evaluation of the Site, including identifying vinyl chloride contamination in a Village of Hoosick Falls wells as attributable to a release from their facility, considering PFOAs in the site scoring, including in the scoring a release below regulatory limits, in determining the population utilizing the contaminated wells as a water supply and the degree the wells were contaminated. Specifically:

- SGPP commented that the overall HRS site score is based on several errors and unsound assumptions that resulted in an inflated site score that is not reflective of site conditions.
- SGPP commented that the EPA should have included information on the soil exposure pathway to complete the record. SGPP added that the soil sampling is relevant in determining whether the Site should be placed on the NPL, considering that the EPA concluded no offsite cleanup work is required.
- SGPP commented that it and the prior owner of the facility, Honeywell International, Inc., have entered into an Order on Consent (Consent Order) with New York State Department of Environmental Conservation (NYDEC), and the EPA should leave the Site in the State of New York cleanup program.
- SGPP asserted that placing the Site on the NPL is unnecessary and will delay ongoing remedial activities. SGPP stated that the presence of PFOA at the Site is already being addressed without intervention by the EPA.
- SGPP commented that the Site does not pose risk to the public. SGPP indicated that listing this Site on the NPL is based on such little evidence of hazardous substances at the Site that the listing in and of itself is unprecedented.
- SGPP commented that PFOA is not a CERCLA hazardous substance, and the EPA has not promulgated any binding drinking water standards for it.

- SGPP also commented that TCE or any other CERCLA hazardous substances have not been detected above any applicable standards in any drinking water supply well.
- SGPP commented that vinyl chloride in PSW 6 is not attributable to alleged historical releases of TCE at the SGPP site. SGPP asserted that the EPA has not presented sufficient evidence to support the degradation of TCE at the Site in MW-6 at the facility to the vinyl chloride detected in PSW 6. SGPP contended that the claim that a single detection of vinyl chloride at a concentration of 1.3 µg/L in PSW 6 is attributable to low levels of TCE in ground water at the Site is not supported by the scientific data. SGPP surmised that the EPA's analysis of the migration of vinyl chloride in the aquifer is flawed and is inconsistent with claims made in the HRS documentation record at proposal.
- SGPP commented that the EPA should not have assigned a pathway hazardous waste quantity of 100 to the ground water migration pathway. SGPP asserted that the EPA acknowledged the actual calculated hazardous waste quantity for the ground water pathway at the Site is 1, not 100.
- SGPP also commented that the EPA should not have assigned a toxicity factor value of 10,000 to PFOA because the reference dose (RfD) for PFOA is premised upon inappropriate assumptions such as the developmental effects upon which the reference dose is based are transient developmental effects that do not alter the well-being of the mice. SGPP also claimed that there are inconsistencies in the data from the experimental animal study; the EPA incorporated inappropriate uncertainty factors into its derivation of the reference dose; the EPA has not found adequate evidence to assign a regulatory classification to PFOA as a likely carcinogen, so there is no basis that a maximum toxicity factor of 10,000 should be applied to PFOA as is applied to known carcinogens; and the EPA has not identified any epidemiological studies regarding PFOA and potential adverse human health effects that it believes are sufficiently reliable to develop regulatory ground water or drinking water standards.
- SGPP additionally contended that there are no Level I concentrations (concentrations meeting observed release criteria and above HRS benchmarks) attributable to the Site in any target well, and the status and pumping capacity of Well PSW 6 was inaccurately represented in the HRS scoring of the Site. SGPP stated that PSW 6 is an emergency back up well, and the population associated with PSW 6 was inaccurately apportioned and should be value of 0 not 13,330.

The commenters' specific challenges to the listing are detailed in the following sections of this support document along with the EPA's responses demonstrating the SGPP site qualifies for placement on the NPL.

3.1 Support for Listing

Comment: The Acting Commissioner of the Office of the Commissioner, New York State Department of Environmental Conservation; State Senator, Kathy Marchione of the 43rd District of New York; Mayor David B. Borge of the Village of Hoosick Falls; Stan Brownell, Chairman, and Lester Goodermote, Legislator, of the Office of the Majority, Rensselaer County Legislature, New York; and five additional commenters supported the placement of the Site on the NPL.

Acting Commissioner Basil Seggos, Office of the Commissioner, New York State Department of Environmental Conservation, also commented that the government agencies charged with protecting public health and the environment must work together on a full investigation of the nature and extent of the PFOA contamination and any necessary cleanup. The Acting Commissioner stated that the Department of Health will remain responsible for all matters related to public health regarding the Site, and he looks forward to continuing collaboration at all levels of the government to address the PFOA contamination.

Kathy Marchione, State Senator, 43rd District, State of New York commented that an NPL designation will support necessary site investigations, empower the EPA to assess the nature and extent of public health and environmental risks associated with the Site, and make the site eligible for long-term cleanup. The State Senator

noted that continued cooperation with Federal, State and local government must be part of the long term solution to address the PFOA contamination in the community.

Mayor David B. Borge of the Village of Hoosick Falls stated that the community showed support for the placement of the Site on the NPL at the October 24, 2016 joint public hearing. He added that during that public forum the EPA representatives and New York State Department of Environmental Conservation (NYDEC) assured the community that the collaborative efforts and resources from both the EPA and NYDEC would continue, and the community would benefit from a full cleanup at no financial cost to the community.

Stan Brownell, Chairman, and Lester Goodermote, Legislator, of the Office of the Majority, Rensselaer County Legislature, New York, also expressed that they look forward to working with the EPA. Mr. Brownell and Mr. Goodermote commented that they expect inclusion of the Site on the NPL will allow contamination at the Site to be addressed and the community to thrive in coming years. Mr. Brownell and Mr. Goodermote stated that, as residents, they recognize the crucial situation the Village currently faces as the discovery of PFOAs has affected the image of the Village, disrupted quality of life in the community and possibly impacted property values. However, they stated that an effective remediation effort can do a great deal to restore the standing of the Village and to address the reasonable concerns regarding health and safety of their fellow residents. Mr. Brownell and Mr. Goodermote added that the resources and compliance powers of the EPA are necessary to investigate and remediate the Site, and a full investigation of the PFOA contamination, including water, air, and soil migrations, is necessary.

Mr. James Donovan, a resident of Hoosick Falls, supported the listing but also requested that the Hoosick Falls landfill be added to the Superfund list. He said his health has been adversely impacted by exposure to PFOA in the Village water supply. Similarly, an anonymous commenter expressed concerns that the former landfill is being overlooked by the EPA. The commenter explained that she lives 2.7 miles from the SGPP site but 0.7 mile from the landfill, and her private well has 70 part per trillion (ppt) of PFOA. The commenter requested that all areas of Hoosick Falls be investigated to ensure safety and security of her family.

An anonymous commenter, while supporting the listing, also requested there be continued investigations at "other pollution sites in Hoosick Falls" including the Village landfill.

Another anonymous commenter also requested that the Federal government continue to investigate other pollution in Hoosick Falls to ensure future generations will not have to address medical and financial impacts due to contaminated soil and water. The commenter indicated that his/her health has been adversely impacted since living in Hoosick Falls, and his/her home is not worth anything.

Mr. John Bozeman stated that Superfund will provide the necessary resources to clean up the Site and guarantee the safety of the Village's drinking water supply. He also commented that the EPA can investigate to determine who the polluters are and hold them accountable. He noted that the American Cancer Society reported that PFOA is a B2 carcinogen. He cited the following document: *American Cancer Society. Teflon and Perfluorooctanoic Acid (PFOA)*. (2016). Retrieved from <http://www.cancer.org/cancer/cancercauses/othercarcinogens/athome/teflon-and-perfluorooctanoicacid--Pfoa>.

Response: The EPA is adding the Saint-Gobain Performance Plastics Site to the NPL. Listing makes a site eligible for remedial action funding under CERCLA, and the EPA will examine the site to determine what response, if any, is appropriate. The EPA will determine the need for using Superfund monies for remedial activities on a site-by-site basis, taking into account the NPL ranking, State priorities, further site investigation, other response alternatives and other factors as appropriate.

Regarding the request for continued investigations at other sites in Hoosick Falls, this listing addresses releases from the SGPP site.

3.2 Scope of the HRS Evaluation

Comment: SGPP commented that the EPA should include the results of the EPA's soil sampling in the Village in the HRS documentation record. It explained that although the EPA did not calculate a soil exposure pathway score for the Site, the EPA should include the results of its soil sampling in the Village to complete the record.

SGPP further stated that the soil sampling is relevant to evaluating whether the Site should be listed on the NPL as one of the EPA's top priorities. SGPP contended that off-site sampling results performed by the EPA to determine whether a cleanup action is needed showed PFOA levels from non-detected to 0.02 parts per million (ppm) which is well below the EPA's soil screening level and from which the EPA then concluded that no-offsite soil cleanup work is required. SGPP cited to SGPP Exhibit 20¹ to support its comment. SGPP noted the following soil sampling event which supported the EPA's conclusion and which it noted is relevant to evaluating whether the Site should be placed on the NPL:

- In the February 2016 soil samples in ball fields and park areas along Waterworks Road and in the Athletic Field near the local ice rink and community pool, PFOA levels in soils ranged from non-detected to 0.0277 ppm, well-below the EPA soil screening level. (SGPP Exhibit 20).
- In the May 2016 soil samples at 33 additional locations including residential properties in the vicinity of the Site, PFOA levels ranged from non-detected to 0.0277 ppm.

Response: The information contained in the SGPP site HRS documentation package was sufficient to document that the Site qualifies for the NPL; none of the additional information regarding a possible threat via the soil exposure pathway suggested by SGPP contradicts the HRS documentation record characterization of the Site, source, observed releases, or targets. If SGPP is suggesting that additional preliminary soils sampling indicate that the Site poses no risk via the soil exposure pathway, a subsequent stage of the Superfund process, the remedial investigation (RI), will characterize conditions and hazards at the Site more comprehensively. This site has been placed on the NPL because it has an HRS score greater than 28.50 and meets all CERCLA and NCP listing criteria.

Regarding SGPP's comment that the Site should be listed on the NPL as one of the EPA's top priorities, the EPA places eligible sites on the NPL pursuant to the Agency's authorities under CERCLA and its associated regulations. CERCLA § 105(a)(8)(a) requires the EPA to determine NPL priorities based on the "relative risk or danger to public health or welfare, or the environment." Consistent with CERCLA, the SGPP site is being placed on the NPL based on an HRS evaluation of the risk relative to other sites being considered for the NPL resulting from the release at this site of hazardous substances to a ground water aquifer and the resulting threat the release poses to the City's drinking water supply. The EPA must balance the need to fully characterize a site with the limited resources available to collect and analyze site data. However, any additional data that characterizes site conditions could provide useful information during the RI. Additionally, the subsequent Superfund remedial investigation and risk assessment will include extensive processes to establish the threat posed via additional migration and exposure pathways.

¹ Exhibit 20 of SGPP comment document (available at EPA docket ID: EPA-HQ-OLEM-2016-0434-0015) is: *Hoosick Falls Update: EPA Soil Sampling at Ballfields, Community Update No. 1* (February 2016), *Hoosick Falls Update: EPA Soil Sampling at Hoosick Falls Athletic Field, Community Update No. 2* (February 2016), *Hoosick Falls Update: EPA Results Show Ballfields & Athletic Field OK to Use, Community Update No. 3* (Spring 2016), *Hoosick Falls Update: EPA Expands Sampling Program in Areas Near McCaffrey Street Facility, Community Update No. 4* (Spring 2016), *Hoosick Falls Update: EPA Expands Sampling Program in Areas Near McCaffrey Street Facility, Community Update No. 4-V2* (Spring 2016), *Hoosick Falls Update: Results from 34 Locations Show No Soil Cleanup Needed at Residential Properties, Football & Recreational Fields, Community Update No. 5* (September 2016).

Further, the HRS does not require scoring all four pathways if scoring those pathways does not change the listing decision. For some sites, data for scoring a pathway are unavailable and obtaining these data would be time-consuming or costly. In other cases, data for scoring some pathways are available, but would only have a minimal effect on the site score. In still other cases, data on other pathways could substantially add to a site score, but would not affect the listing decision. The HRS is a screening model that uses limited resources to determine whether a site should be placed on the NPL for possible Superfund response. A subsequent stage of the Superfund process, the RI, characterizes conditions and hazards at the site more comprehensively.

To the extent practicable, the EPA attempts to score all pathways that pose significant threats. If the contribution of a pathway is minimal to the overall score, in general, that pathway will not be scored. In these cases, the HRS documentation record may include a brief qualitative discussion to present a more complete picture of the conditions and hazards at the site. As a matter of policy, the EPA does not delay listing a site to incorporate new data or score new pathways if the listing decision is not affected.

The HRS is intended to be a “rough list” of prioritized hazardous sites; a “first step in a process--nothing more, nothing less.” *Eagle Picher Indus. v. EPA*, 759 F.2d 922, 932 (D.C. Cir. 1985) (*Eagle Picher II*). The EPA would like to investigate each possible site completely and thoroughly prior to evaluating them for proposal for the NPL, but it must reconcile the need for certainty before action with the need for inexpensive, expeditious procedures to identify potentially hazardous sites. The D.C. Circuit Court of Appeals has found the EPA's approach to solving this conundrum to be “reasonable and fully in accord with Congressional intent.” *Eagle Picher Industries, Inc. v. EPA*, (759 F.2d 905 (D.C. Cir. 1985) *Eagle Picher I*).

Further, the decisions made regarding soil sampling under the EPA Removal program to date, addressed only the acute direct human contact risk to contaminated surface soils. Therefore, because the EPA Removal Program was focused on the direct contact risk, these actions did not necessarily address the impacts to ground water drinking water supplies due to migration from the contaminated soils. Placing this site on the NPL allows the EPA to investigate and address this risk in separate phases of the Superfund process as necessary.

This comment results in no change to the HRS score and no change in the decision to place the Site on the NPL.

3.3 Alternative to Listing/Defer to State

Comment: SGPP stated that it and the prior owner of the facility, Honeywell International, Inc., have entered into an Order on Consent (Consent Order) with New York State Department of Environmental Conservation (NYDEC). SGPP stated it and Honeywell are in the process of remediating the Site and potentially impacted wells and have implemented various remediation measures. SGPP asserted that Federal involvement is not necessary. SGPP requested that the EPA leave the site in the New York State cleanup program and withdraw the listing.

SGPP asked a variety of questions regarding oversight at the Site. It questioned if the National Contingency Plan (NCP) and other Federal regulations apply to the cleanup and if so how will they apply since there are no Federal standards for PFOA? Will the existing Consent Order between SGPP, Honeywell and the NYDEC be superseded by some other agreement and if so what will take its place and how long will it take to finalize? Will the EPA perform work at the Site and if so which portion and why? SGPP contended that uncertainty and confusion can be avoided by leaving the Site in the New York State cleanup program.

Response: Adding the SGPP site to the NPL is an appropriate next step in the Superfund process. The HRS site score of above 28.50 represents the EPA's assessment that the relative risk posed by the Site demonstrates that the Site qualifies for placement on the NPL and warrants further investigation under the Superfund program.

The State of New York has requested the Site be placed on the NPL. In a letter dated January 14, 2016, (docket ID EPA-HQ-QLEM-2016-0434-0007), prior to the placement of the Site on the NPL, Acting Commissioner Mr. Basil Seggos, Office of the Commissioner, New York State Department of Environmental Conservation, stated:

The detection of perfluorooctanoic acid (PFOA) in the public water supply of the Village of Hoosick Falls (Village) in Rensselaer County, New York is deeply concerning....

As the government agencies charged with protecting public health and the environment, it is imperative that DOH, the New York State Department of Environmental Conservation (DEC), and the EPA work together on a full investigation of the nature and extent of PFOA contamination and, then, on any necessary cleanup. DEC and DOH stand ready to assist in this investigation by the EPA.

I am proposing that EPA, after conducting an investigation, nominate for inclusion on the National Priorities List the Saint-Gobain Performance Plastics Corp. McCaffrey Street Plant Site in the Village of Hoosick Falls (EPA facility No. NYD000829598), where high levels of PFOA in groundwater have been observed, and any other source of a release of PFOA in the Village or Town of Hoosick Falls that may be identified during the course of the investigation.

On May 3, 1995, the EPA issued its "Guidance on Deferral of NPL Listing Determinations While States Oversee Response Actions." The EPA developed the guidance in an effort to enhance the State role in addressing sites. The deferral program is an administrative tool to enable States and Tribes, under their own laws, to respond at sites that the EPA would otherwise not soon address. Because of the great differences in State and Tribal capabilities; however, the EPA implements the guidance in a flexible manner. Hence, Regions may act at variance from certain provisions of the guidance.

Pursuant to guidance and the request by the State of New York, the EPA has decided that deferral to the State of New York is not appropriate in this case.

This comment results in no change to the HRS score and no change in the decision to place the Site on the NPL.

3.4 Need for Listing and Resulting Delay

Comment: SGPP submitted comments questioning the need for and purpose of placing the SGPP site on the NPL and indicated that placement of this site on the NPL will serve to delay cleanup. SGPP commented that listing is unnecessary and would impede already ongoing remedial activities.

SGPP stated that the presence of PFOA at the Site is already being addressed without intervention by the EPA. It claimed that it has spent nearly the last two years working cooperatively with the Village and State officials to reduce or eliminate PFOA at the Site and in the local water supply without any direction or action from the EPA.

SGPP further claimed that "on March 30, 2016, NYDOH announced that the Village's water was non-detect for PFOA as of March 13, 2016, and determined that Village residents 'may use the water for any and all uses, including drinking and cooking.'" (SGPP cited to Exhibits 4 through 8 of its comment document available at EPA docket ID: EPA-HQ-OLEM-2016-0434-0015.)²

²Exhibit 4 of SGPP comment document is: The Village of Hoosick Falls Municipal Water public release statements

Exhibit 5 of SGPP comment document is: Confidential, Calgon Carbon Corporation, Pittsburgh, PA, technical service Report No. 20150420, prepared for Hoosick falls, Hoosick, NY, May 22, 2015.

Exhibit 6 of SGPP comment document is: Department of Environmental Conservation, New York State Department of

SGPP added that it and Honeywell are already performing a RI/FS at the Site under the direct oversight of the NYDEC pursuant to a Consent Order that was entered in June 2016. (SGPP cites Reference 18³ of the HRS documentation record at proposal.)

Response: The need for placing this site on the NPL has not been negated by the actions taken by SGPP and is consistent with the purpose of the NPL. In addition, the act of placing this site on the NPL need not delay any ongoing or planned site remediation. As discussed below, SGPP can work with the EPA and the State of New York to avoid unnecessary delays.

First, the EPA considers that the promulgation of this site to the NPL fulfills the purpose of the NPL. The primary purpose of the NPL is stated in the legislative history of CERCLA (Report of the Committee on Environment and Public Works, Senate Report No. 96-848, 96th Cong., 2d Sess. 60 [1980]), as follows (in relevant part): “The priority list serves primarily informational purposes, identifying for the States and the public those facilities and sites or other releases which appear to warrant remedial actions.” The EPA has clearly, via this listing, identified for the States and the public the release that is currently scored using the HRS. Listing also is a necessary step to enable the use of CERCLA funds as needed to ensure that Site cleanup moves forward.

Second, regarding the need for placing this site on the NPL, the response actions taken to remove the immediate risks to the public do not eliminate this site from NPL consideration because these actions do not show that the contaminated drinking water supply (contaminated aquifer) does not still exist. The drinking water samples show no detection of PFOA were collected after being treated by the granular activated carbon filtration system at the water treatment facility, from within the drinking water distribution system holding tanks, and from taps at homes on several street locations. (See Exhibits 4 and 8 of SGPP comments available at EPA docket ID: EPA-HQ-OLEM-2016-0434-0015.) However, sampling of water from the aquifer, at a point prior to filtration to remove PFOA, has not confirmed that the aquifer is not contaminated with PFOA. As long as the aquifer remains contaminated, a risk exists that warrants further investigation. Further, the extent of contamination of PFOA, TCE, 1,2-DCE and vinyl chloride, known to be present in the aquifer, will be more fully determined at a subsequent stage of the Superfund process, the remedial investigation (RI).

Third, placement of the Site on the NPL does not necessarily lead to delay of planned response actions or associated negotiations. These actions can be considered in other steps of the Superfund process. Consistent with CERCLA, the EPA has in place an orderly procedure for identifying sites where releases of substances addressed under CERCLA have occurred or may occur, placing such sites on the NPL, evaluating the nature and extent of the threats at such sites, responding to those threats, and deleting sites from the NPL. The purpose of the initial two steps is to develop the NPL, which identifies for the States and the public those sites that appear to warrant remedial action (56 FR 35842, July 29, 1991). The evaluation or RI/FS phase involves on-site testing to assess the nature and extent of the public health and environmental risks associated with the site and to determine what CERCLA-funded remedial actions, if any, may be appropriate. After a period of public comment, the EPA responds to those threats by issuing a Record of Decision which selects the most appropriate alternative. The

Environmental Conservation Secures Agreement that holds Saint Gobain & Honeywell Responsible for PFOA Contamination in Hoosick Falls Area, June 3, 2016.

Exhibit 7 of SGPP comment document is: EPA Statement on Private Wells in the Town of Hoosick and Village of Hoosick Falls, NY, January 28, 2016.

Exhibit 8 of SGPP comment document is: Letter dated March 30, 2016 from Commissioner Howard A. Zuker, M.D., J.D., New York Department of Health, to The Honorable David B. Borge, Village of Hoosick Falls.

³ Reference 18 of the HRS documentation record at proposal is: New York State Department of Environmental Conservation (NYSDEC) State Superfund Program (ECL §27-1301 et seq.). Order on Consent and Administrative Settlement, Index No. CO 4-20160212-18, In the Matter a Remedial Program for PFOA impacting the Village of Hoosick Falls Municipal Water Supply, private drinking water wells in the Town of Hoosick, and Saint-Gobain McCaffrey Street (DEC Site No. 442046) and Saint-Gobain Liberty Street Site (DEC Site No. 442048). June 3, 2016.

selected remedy is implemented during the remedial design/remedial action phase. Finally, the site may be deleted from the NPL when the EPA determines that no further response is appropriate.

Therefore, any site investigation work, as well as any remediation undertaken by SGPP and other potentially responsible parties (PRPs) performed to date and that which is currently proceeding can be considered in other steps of the Superfund remediation process, such as when performing a remedial investigation or a Superfund risk assessment for the Site. Then, based on the findings of the risk assessment, a determination of what further remedial actions, if any, are necessary will be made. If SGPP or any designated PRP wishes to expedite cleanup efforts, it may continue negotiations with the EPA and undertake removal actions under supervision of the EPA and pursuant to appropriate agreements with governmental authorities (under enforcement authorities of CERCLA or those of other statutes). Further, as stated in section 3.3, Alternative to Listing/Defer to State, of this support document, the State of New York supports the placement of the Site on the NPL as is evident in a correspondence dated January 14, 2016, from Acting Commissioner Mr. Basil Seggos, Office of the Commissioner, New York State Department of Environmental Conservation (docket ID EPA-HQ-QLEM-2016-0434-0007).

This comment results in no change to the HRS score and no change in the decision to place the Site on the NPL.

3.5 Risk

Comment: SGPP asserted that the Site does not pose risk to the public or the environment. SGPP indicated that listing this Site on the NPL is based on such little evidence of hazardous substances at the Site that the listing in and of itself is unprecedented. SGPP made the following claims:

- With the exception of one ground water monitoring well in which TCE was detected at 13 parts per billion (ppb) in May 2016, there is not a single CERCLA hazardous substance present above applicable ground water or drinking water standards anywhere at the Site.
- Only vinyl chloride was detected in a single well (PSW 6) at a concentration of 1.3 ppb which is approximately ½ of the applicable maximum contaminant level (MCL) and it has not been detected by the Village in any of its supply wells during its annual monitoring between 2004 and 2009, in 2011, or in 2014, 2016.
- PFOA at the Site does not present any risk to health or the environment.
- There is no need for further investigation or remedial action of the PFOA by the EPA and therefore no sound basis for listing the Site on the NPL. On March 30, 2016, NYDOH announced that the Village's water was non-detect for PFOA as of March 13, 2016, and Village residents 'may use the water for any and all uses, including drinking and cooking.'

Response: The HRS site score above 28.50 demonstrates that the Site poses a sufficient relative risk to warrant placement on the NPL. SGPP has not documented that all unacceptable risk posed by the release from the SGPP facility has been eliminated by their actions. Listing makes a site eligible for remedial action funding under CERCLA, and the EPA will examine the site to determine site-specific risk and what response, if any, is appropriate as part of a separate stage of the Superfund process. The NPL is intended primarily to guide the EPA in determining which sites warrant further investigation to assess the nature and extent of public health and environmental risks associated with a release of hazardous substances, pollutants or contaminants. See, 81 FR 62428-62433 (Proposed Rule for Saint-Gobain Performance Plastics, September 9, 2016); see also 55 FR 51532 (Final Rule, Hazard Ranking System, December 14, 1990). CERCLA § 105(a)(8)(a) requires the EPA to determine NPL priorities among sites based on the "relative risk or danger to public health or welfare, or the environment." The criteria the EPA applies to determine this relative risk or danger is codified in the HRS, and it is the Agency's primary tool for deriving a site score based on the factors identified in CERCLA.

The HRS evaluation and a score above 28.50 represent the EPA's determination that the Site may pose a relative risk or danger to human health and the environment and warrants further investigation under CERCLA.

As part of the standard Superfund process and once the Site is on the NPL, the investigations performed to date to characterize the Site will be evaluated for completeness. Further information will be collected if deemed necessary to adequately characterize the risks posed by the Site, and based on this information, a risk assessment decision will be made determining what, if any, remedial action is necessary to protect human health and the environment.

The HRS documentation record at proposal establishes that the SGPP site poses sufficient relative risk to human health to warrant inclusion on the NPL, and it establishes that there could be unacceptable site specific risk associated with the Site. Contaminated soil and ground water have been documented at the Site, and drinking water target wells are contaminated with vinyl chloride above the cancer risk screening concentration and with PFOA at a level associated with unacceptable health effects. (See Figure 2 and pages 19-28 and 33-44 of the HRS documentation record at proposal.)

Regarding other released hazardous substances, TCE, vinyl chloride, PFOA, 1,2-DCE and PCBs were documented in sources and/or the observed release at the Site. (See pages 23 to 26, 33 to 49 of the HRS documentation record at proposal; see sections 3.7, Eligibility of PFOA for HRS Evaluation, and 3.8, Releases Below Regulatory Limits, of this support document).

In addition, a release of vinyl chloride was detected in PSW 6 above the cancer risk screening concentration (pages 38, 39 and 50 of the HRS documentation record at proposal). Also, PFOA was found in release concentrations in PSW 7 (pages 42, 43 and 51 of the HRS documentation record at proposal; page 9 of Exhibit 15⁴ of SGPP'S comment document, EPA docket ID: EPA-HQ-OLEM-2016-0434-0015). PFOA was detected at a level in this well that could lead to exposures above that associated with health effects. PSW 3 was also found to be contaminated with PFOA. (See sections 3.4, Need for Listing and Resulting Delay, and 3.9, Observed Releases, of this support document for additional information.)

Regarding the need for further investigation, the EPA's actions to evaluate the Site using the HRS and list the SGPP site are consistent with the requirements of CERCLA and the statutory purpose of the NPL. That the granular activated carbon (GAC) filtration system installed at the municipal water supply is currently removing PFOA from drinking water prior to water being distributed for use to residents does not negate that a release of hazardous substances, both PFOA and vinyl chloride in the aquifer has been documented. (See section 3.4, Need for Listing and Resulting Delay, of this support document for additional information.) Until the contamination in the aquifer has been permanently removed, the risk associated with the release to the aquifer has not been eliminated.

This comment results in no change to the HRS score and no change in the decision to place the Site on the NPL.

3.6 Economic Impact-Stigma of Listing

Comment: Mr. Brownell and Mr. Goodermote stated that the discovery of PFOAs has affected the image of the Village, disrupted quality of life in the Community and possibly impacted property values, but that an effective remediation effort can do a great deal to restore the standing of the Village and address the reasonable concerns regarding health and safety of their fellow residents. An anonymous commenter indicated that his/her home is not worth anything.

⁴ Health Advisory for Perfluorooctanoic Acid (PFOA) (USEPA, May 2016) [also available at: https://www.epa.gov/sites/production/files/2016-05/documents/pfoa_health_advisory_final-plain.pdf]

Response: Inclusion of a site or facility on the NPL reflects the EPA's judgment that a significant release or threat of release has occurred and that the site is a priority for further investigation under CERCLA. The EPA notes that there are both costs and benefits that can be associated with listing a site. Among the benefits are increased health and environmental protection as a result of increased public awareness of potential hazards. In addition to the potential for Federally financed remedial actions, the addition of a site to the NPL could accelerate privately financed, voluntary cleanup efforts. Listing sites as national priority targets also may give States increased support for funding responses at particular sites. As a result of the additional CERCLA remedies, there will be lower human exposure to high-risk chemicals and higher quality surface water, ground water, soil, and air. Therefore, it is possible that any perceived or actual negative fluctuations in property values or development opportunities that may result from contamination may also be countered by positive fluctuations when a CERCLA investigation and any necessary cleanup are completed.

This comment results in no change to the HRS score and no change in the decision to place the Site on the NPL.

3.7 Eligibility of PFOA for HRS Evaluation

Comment: SGPP asserted that per 42 U.S.C. § 9602(a), PFOA is not a CERCLA hazardous substance. It explained that despite having studied PFOA for years, the EPA has not designated PFOA as a hazardous substance under CERCLA or any other federal laws, nor has the EPA promulgated any binding ground water or drinking water standards for PFOA. SGPP then asserted that the EPA should not be listing the Site on the NPL based upon the presence of PFOA in ground water at the Site.

Response: PFOA was correctly identified as qualifying as a CERCLA pollutant or contaminant at the SGPP site, not a CERCLA hazardous substance, and, therefore, can be considered in the HRS site evaluation, as explained below. Furthermore, there is no requirement that a drinking water standard must be promulgated for a substance for it to be included in an HRS evaluation, only that it meet the CERCLA definition of a pollutant or contaminant.

CERCLA Section 101(33) defines "pollutant or contaminant" as including but not limited to,

any element, substance, compound, or mixture, including disease-causing agents, which after release into the environment and upon exposure, ingestion, inhalation, or assimilation into any organism, either directly from the environment or indirectly by ingestion through food chains, will or may reasonably be anticipated to cause death, disease, behavioral abnormalities, cancer, genetic mutation, physiological malfunctions (including malfunctions in reproduction) or physical deformations, in such organisms or their offspring.

Hazardous substances are defined for HRS purposes in HRS Section 1.1, *Definitions*, as,

CERCLA hazardous substances, pollutants, and contaminants as defined in CERCLA sections 101(14) and 101(33), except where otherwise specifically noted in the HRS. [55 FR 51586, December 14, 1990].

Therefore, while a substance may not be a CERCLA hazardous substance, it can be considered a HRS hazardous substance because the HRS defines pollutants and contaminants to be HRS hazardous substances.

PFOA can be considered a pollutant or contaminant at this site because it is at a concentration at the Site that could cause increase total cholesterol, thyroid disease, decreased response to vaccines, and pregnancy-related hypertension or preeclampsia (pages 241 to 242, 253 to 257 of Reference 13, *Health Effects Support Document*

for Perfluorooctanoic Acid (PFOA) (EPA, 2016)⁵). PFOA is clearly in the release from the SGPP facility. It was found in quantifiable levels in 2 of the 3 drinking water wells evaluated in the scoring of the Site. The PFOA concentration in a sample from PSW 7 was found to be 520 ng/L (0.52 µg/L), and the PFOA concentration in a sample from PSW 3 was found to be 140 ng/L (0.14 µg/L). PFOA has also been documented in monitoring wells at the Site at concentrations ranging from 570 ng/L to 18,000 ng/L (0.57 µg/L to 18 µg/L) (pages 41 – 43 of the HRS documentation record at proposal).

On pages 11 and 12 of the HRS documentation record at proposal, the EPA documented that the PFOA concentration in the sample from PSW 7 and in other samples from the Site are at levels that can cause adverse health effects, and, therefore, PFOA can be used in HRS scoring. It states:

The May 2016 Health Effects Support Document for PFOA established a Reference Dose (RfD) value of 0.00002 milligrams per kilogram per day (mg/kg/day) [Ref. 13, p. 256]. The calculated PFOA dose in Village Well 7 is 0.000025 mg/kg/day [Ref. 59, pp. 1–4]. The calculated PFOA dose in ground water can be up to 0.000897 mg/kg/day [Ref. 59, pp. 1–4]. Both calculated dose values exceed the RfD [Ref. 59, pp. 1–4]. Therefore, the TSCA submittal by SGPP documents an observed release by direct observation of PFOA at a concentration that likely results in harm to any organism following exposure [Ref. 59, pp. 1–4]. The exceedances of the RfD establishes PFOA as a Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) pollutant or contaminant (i.e., any element, substance, compound, or mixture, including disease-causing agents, which after release into the environment and upon exposure, ingestion, inhalation, or assimilation into any organism, either directly from the environment or indirectly by ingestion through food chains, will or may reasonably be anticipated to cause death, disease, behavioral abnormalities, cancer, genetic mutation, physiological malfunctions [including malfunctions in reproduction] or physical deformations, in such organisms or their offspring) [Ref. 1, Section 3.1.1; 46, pp. 14–15; 59, pp. 1–4].

This comment results in no change to the HRS score and no change in the decision to place the Site on the NPL.

3.8 Releases Below Regulatory Limits

Comment: SGPP stated that TCE or any other CERCLA hazardous substances have not been detected above any applicable standards in any drinking water supply well.

Response: The identification of PFOA, TCE and vinyl chloride found in soils and in ground water documented in the HRS documentation record at proposal is eligible for HRS evaluation because the identification of a release of these substances is consistent with CERCLA and the HRS. Furthermore, if SGPP is specifically implying that the identification of HRS observed releases of vinyl chloride and PFOA are incorrect because the levels of these substances were below drinking water standards, this challenge is also incorrect.

On July 16, 1982, when responding to public comments on the proposed (original) HRS (47 FR 31188), and again on September 8, 1983 (48 FR 40665), the EPA rejected the idea that releases within regulatory limits should not be considered in HRS scoring of a site in general or specifically when identifying “observed releases” under the HRS. As the EPA noted in 1982:

[E]mission or effluent limits do not necessarily represent levels which cause no harm to public health or the environment. These limitations are frequently established on the basis of economic impacts or achievability.

⁵ Health Effects Support Document for Perfluorooctanoic Acid (PFOA) (EPA, 2016) is also available at: https://www.epa.gov/sites/production/files/2016-05/documents/pfoa_hesd_final-plain.pdf.

By contrast, an observed release represents a 100 percent likelihood that substances can migrate from the site (47 FR 31188, July 16, 1982).

Section 2.3 of the revised HRS (55 FR 51589, December 14, 1990) states that an observed release can be established either by direct observation or by chemical analysis. An observed release by chemical analysis has occurred when a contaminant is measured significantly above background level if some portion of the release is attributable to the site. Although contaminant levels may be lower than regulatory limits, an observed release has nevertheless occurred if the measured levels are significantly higher than background levels. The HRS does, however, consider whether releases are above regulatory limits in evaluating target populations, increasing by a factor of 10 the weight assigned populations exposed to contaminants above regulatory limits.

Of course, the observed release factor alone is not intended to reflect the hazard presented by the particular release. Instead, the hazard of the site is approximated by the total HRS score, which incorporates the observed release factors with other factors such as waste characteristics (including waste quantity, toxicity, and mobility) and targets. This total HRS score reflects the hazard of the site relative only to the other sites that have been scored. The actual degree of contamination and its effects are more fully determined during the remedial investigation that typically follows listing.

Furthermore, vinyl chloride was detected in a drinking water well above an HRS health based benchmark. Vinyl chloride was documented in PSW 6 at a concentration above the HRS cancer risk screening level for drinking water. Vinyl chloride in PSW 6 was documented at a concentration of 1.3 µg/L, and the HRS cancer risk screening concentration for vinyl chloride is 2.1×10^{-2} µg/L (or 0.021 µg/L) (page 50 of the HRS documentation record at proposal). See section 3.11.1, Level I Concentration, of this support document for additional information.

This comment results in no change to the HRS score and no change in the decision to place the Site on the NPL.

3.9 Observed Releases

SGPP comments on the observed release to ground water are discussed below in the following subsections:

- 3.9.1 Observed Releases –Applicable Standards
- 3.9.2 Observed Releases –Attribution

3.9.1 Observed Releases – Applicable Standards

Comment: SGPP stated that TCE or any other CERCLA hazardous substances have not been detected above any applicable standards in any drinking water supply well.

Response: The EPA identified observed releases of TCE, vinyl chloride and PFOA to ground water according to the criteria in the HRS. As identified above in section 3.8, Releases Below Regulatory Limits, of this support document, neither CERCLA nor the HRS requires that the concentration establishing significant increases be above any applicable standards for an observed release to ground water to be eligible for evaluation at a Site. See section 3.9.2, Observed Releases - Attribution, of this support document for discussion of attribution of the releases to the Site.

The directions for establishing observed releases to ground water are in HRS Sections 3.1, 3.1.1 and 2.3. None of these sections require the concentration in the observed release samples to be above regulatory limits.

In evaluating the likelihood of release factor, HRS Section 3.1, *Likelihood of release*, states:

For an aquifer, evaluate the likelihood of release factor category in terms of an observed release factor or a potential to release factor.

In establishing an observed release, HRS Section 3.1.1, *Observed release*, states:

Establish an observed release to an aquifer by demonstrating that the site has released a hazardous substance to the aquifer. Base this demonstration on either:

- Direct observation—a material that contains one or more hazardous substances has been deposited into or has been observed entering the aquifer.
- Chemical analysis—an analysis of ground water samples from the aquifer indicates that the concentration of hazardous substance(s) **has increased significantly above the background concentration for the site** (see section 2.3). Some portion of the significant increase must be attributable to the site to establish the observed release, except: when the source itself consists of a ground water plume with no identified source, no separate attribution is required. [Emphasis added].

As referenced in HRS Section 3.1.1, quoted above, HRS Section 2.3, *Likelihood of release*, further directs to:

Establish an observed release either by **direct observation of the release of a hazardous substance into the media being evaluated** (for example, surface water) or by **chemical analysis** of samples appropriate to the pathway being evaluated (see sections 3, 4, and 6). **The minimum standard to establish an observed release by chemical analysis is analytical evidence of a hazardous substance in the media significantly above the background level. Further, some portion of the release must be attributable to the site. Use the criteria in Table 2–3 as the standard for determining analytical significance....** [Emphasis added].

HRS Table 2-3 outlines the criteria to determine analytical significance when establishing a significant increase. It states:

TABLE 2–3—OBSERVED RELEASE CRITERIA FOR CHEMICAL ANALYSIS

Sample Measurement < Sample Quantitation Limit^a
No observed release is established.
Sample Measurement ≥ Sample Quantitation Limit^a
An observed release is established as follows:
<ul style="list-style-type: none"> • If the background concentration is not detected (or is less than the detection limit), an observed release is established when the sample measurement equals or exceeds the sample quantitation limit.^a • If the background concentration equals or exceeds the detection limit, an observed release is established when the sample measurement is 3 times or more above the background concentration.

^a If the sample quantitation limit (SQL) cannot be established, determine [sic] if there is an observed release as follows:
 —If the sample analysis was performed under the EPA Contract Laboratory Program, use the EPA contract-required quantitation limit (CRQL) in place of the SQL.
 —If the sample analysis is not performed under the EPA Contract Laboratory Program, use the detection limit (DL) in place of the SQL.

In the HRS documentation record at proposal, the EPA identified both observed releases by direct observation and by chemical analyses from the SGPP facility according to the HRS requirements cited above.

Observed release by direct observation

Page 33 of the HRS documentation record at proposal documents an observed release of PFOA by direct observation to the aquifer based on the finding that a material that contains one or more hazardous substances has been deposited into the aquifer at the Site. Pages 33 of the HRS documentation record at proposal states:

Information provided to EPA by SGPP documents an observed release by direct observation to the aquifer being evaluated. On December 12, 2014, SGPP became aware of the presence of PFOA in the [V]illage [of Hoosick Falls] drinking water supply and obtained the analytical results on December 15, 2014 [Ref. 19, p. 1]. On December 30, 2014, counsel for SGPP submitted notification to EPA under the Section 8(e) of TSCA (15 U.S.C. § 2601 *et seq.*) regarding the presence of PFOA in the Village public drinking water supply; PFOA analytical results for the [V]illage wells were attached to the notification [Ref. 19, pp. 1–10]. The notification acknowledges that SGPP processed fluoropolymers that were made with PFOA at a facility within the [V]illage [Ref. 19, p. 1]. Section 8(e) of TSCA requires any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment to immediately notify EPA of such information [Ref. 31, pp. 32, 33].

The May 2016 Health Effects Support Document for PFOA established an RfD value of 0.00002 mg/kg/day [Ref. 13, p. 256]. The calculated PFOA dose in the Village Well 7 is 0.000025 mg/kg/day [Ref. 59, pp. 1–4]. The calculated PFOA dose in ground water can be up to 0.000897 mg/kg/day [Ref. 59, pp. 1–4]. Both calculated dose values exceed the RfD [Ref. 59, pp. 1–4]. Therefore, the TSCA submittal by SGPP documents an observed release by direct observation of PFOA at a concentration that likely results in harm to any organism following exposure [Ref. 59, pp. 1–4]. The exceedances of the RfD establishes PFOA as a CERCLA pollutant or contaminant [Ref. 1, Section 3.1.1; 46, pp. 14–15; 59, pp. 1–4].

In June 2016, SGPP and NYSDEC State Superfund Program entered into an Order on Consent and Administrative Settlement [Ref. 18, pp. 1–31]. The Order designates the McCaffrey Street facility SGPP [the location of the Saint-Gobain Performance Plastics site] as a “significant threat to public health or the environment” [Ref. 18, p. 4]. Therefore, the Order directs SGPP to prepare and submit an RI/FS work plan for the McCaffrey Street facility to NYSDEC that includes a study and assessment of alternatives to eliminate or reduce PFOA in the [municipal water supply] MWS [Ref. 18, p. 4].

Observed release by chemical analysis

An observed release by chemical analysis was identified based on a significant increase in PFOA, TCE and vinyl chloride (VC) levels and that at least part of the significant increase was due to a release from the Site. Pages 33 through 48 of the HRS documentation record at proposal document an observed release of PFOA, TCE and vinyl chloride by chemical analysis to the aquifer. The concentration of these substances were found to be significantly increased above background levels established for the Site on pages 33 to 44 of the HRS documentation record at proposal. Figures 2 and 3 on pages 13 and 14 of the HRS documentation record at proposal show the sample locations. See also Figures 1 and 2 of this support document. A summary table showing the background levels and observed release concentrations for TCE, vinyl chloride and PFOA extracted from pages 35 to 44 of the HRS documentation record at proposal is provided below:

BACKGROUND SAMPLE RESULTS – TCE						
Field Sample ID	CLP Sample ID	Hazardous Substance	Date Sampled	Result (µg/L)	RDL* (µg/L)	Reference(s)
SGPP-MW05	BD3E9	TCE	5/11/16	5.0 U	5.0	22, p. 33; 23, p. 133; 33, p. 8; 35, pp. 6–10, 50, 140; 47, pp. 5, 325
SGPP-MW06 (Duplicate of SGPP-MW05)	BD3F0	TCE	5/11/16	5.0 U	5.0	22, p. 33; 23, p. 133; 33, p. 8; 35, pp. 6–10, 58, 141; 47, pp. 5, 335
µg/L = micrograms per liter RDL = reporting detection limit U = The analyte was analyzed for, but was not detected at a level greater than or equal to the level of the adjusted CRQL for sample and method. *The RDL for each result is the CRQL adjusted for sample and method [Ref. 33, p. 8]. Since the samples were analyzed through CLP, these adjusted CRQLs are used in place of the HRS-defined SQL [Ref. 1, Sections 1.1 and 2.3].						
OBSERVED RELEASE SAMPLE RESULTS – TCE						
Field Sample ID	CLP Sample ID	Hazardous Substance	Date Sampled	Result (µg/L)	RDL* (µg/L)	Reference(s)
SGPP-MW03	BD3E7	TCE	5/11/2016	13	5.0	22, p. 33; 23, p. 134; 33, p. 8; 35, pp. 6–10, 36, 138; 47, pp. 4, 304
µg/L = micrograms per liter RDL = reporting detection limit *The RDL for each result is the CRQL adjusted for sample and method [Ref. 33, p. 8]. Since the samples were analyzed through CLP, these adjusted CRQLs are used in place of the HRS-defined SQL [Ref. 1, Sections 1.1 and 2.3].						
<i>Notes on samples</i> <ul style="list-style-type: none"> • Release sample concentration is compared to the maximum RDL for non-detect background samples. • Sampling Methods: The background and release samples were all collected by EPA from monitoring wells installed by SGPP at the McCaffrey Street facility that are screened in the same hydrologic unit, using an EPA SOP, during the same sampling event in May 2016 [Figure 2; Ref. 7, pp. 204, 206, 211, 213; 22, pp. 31–33; 23, pp. 47–50, 133–134; 30, pp. 46–50, 56–58]. • Analytical Procedures: The background and release samples were all analyzed for Organic TAL VOC parameters via EPA CLP SOW SOM02.3 (low/medium concentration) by the same laboratory (Chemtech Consulting Group of Mountainside, New Jersey) [Ref. 23, pp. 1, 3–4, 133–134; 47, pp. 1, 304, 325]. The chemical analyses were coordinated through the EPA CLP; EPA validated the data according to EPA Region 2 data validation guidelines (SDG: BD3E5) [Ref. 35, pp. 1, 6–10]. 						

BACKGROUND SAMPLE RESULTS – VC						
Field Sample ID	CLP Sample ID	Hazardous Substance	Date Sampled	Result (µg/L)	RDL* (µg/L)	Reference(s)
SGPP-DW02	BD3G2	VC	5/16/2016	0.50 U	0.50	22, p. 37; 23, p. 148; 33, p. 8; 43, pp. 2–6, 33, 116; 48, pp. 4, 58
SGPP-DW04*	BD3G4	VC	5/16/2016	0.50 U	0.50	22, p. 37; 23, p. 148; 33, p. 8; 43, pp. 2–6, 49, 118; 48, pp. 4, 79
SGPP-DW01	BD3G1	VC	5/16/2016	0.50 U	0.50	22, p. 37; 23, p. 147; 33, p. 8; 43, pp. 2–6, 28, 115; 48, pp. 3, 48
<p>* Environmental duplicate of SGPP-DW02</p> <p>µg/L = micrograms per liter</p> <p>RDL = reporting detection limit</p> <p>U = The analyte was analyzed for, but was not detected at a level greater than or equal to the level of the adjusted CRQL for sample and method.</p> <p>*The RDL for each result is the CRQL adjusted for sample and method [Ref. 33, p. 8]. Since the samples were analyzed through CLP, these adjusted CRQLs are used in place of the HRS-defined SQL [Ref. 1, Sections 1.1 and 2.3].</p>						
OBSERVED RELEASE SAMPLE RESULTS – VC						
Field Sample ID	CLP Sample ID	Hazardous Substance	Date Sampled	Result (µg/L)	RDL* (µg/L)	Reference(s)
SGPP-DW03	BD3G3	VC	5/17/2016	1.3	0.50	22, p. 38; 23, p. 152; 43, pp. 3–6, 39, 117; 48, pp. 7, 68
<p>µg/L = micrograms per liter</p> <p>RDL = reporting detection limit</p> <p>*The RDL for each result is the CRQL adjusted for sample and method [Ref. 33, p. 8]. Since the samples were analyzed through CLP, these adjusted CRQLs are used in place of the HRS-defined SQL [Ref. 1, Sections 1.1 and 2.3].</p> <p><i>Notes on samples</i></p> <ul style="list-style-type: none"> • Release sample concentration is compared to the RDLs reported for the non-detect background samples. • Sampling Methods: The background and release samples were all collected by EPA from the three active village wells via the raw water sampling spigot within the Hoosick Falls water treatment plant, that withdraw water from the same hydrologic unit, using an EPA SOP, during the same sample event in May 2015 [Figure 3; Ref. 6, pp. 12–13, 53–54; 8, p. 2; 22, pp. 37–38, 58; 23, pp. 147–148, 152; 28, pp. 1, 8, 13, 24–25]. • Analytical Procedures: The background and release samples were all analyzed for Organic TAL VOC parameters via EPA CLP SOW SOM02.3 (trace concentration) by the same laboratory (Chemtech Consulting Group of Mountainside, New Jersey) [Ref. 23, pp. 1, 147–148, 152; 47, pp. 1, 48, 58, 68, 79]. The chemical analyses were coordinated through the EPA CLP; EPA validated the data according to EPA Region 2 data validation guidelines (SDG: BD3F5) [Ref. 35, pp. 1, 3–6]. 						

SGPP FACILITY BACKGROUND SAMPLE RESULTS – PFOA						
Field Sample ID	Laboratory Sample ID	Hazardous Substance	Date Sampled	Result (ng/L)	MDL* (ng/L)	Reference(s)
SGPP-MW01D	K1605066-004	PFOA	5/11/16	40	0.27	22, p. 33; 23, p. 143; 55, pp. 9, 16
ng/L = nanograms per liter MDL = method detection limit * For HRS purposes, the DL used is the MDL, which is the lowest concentration of analyte that a method can detect reliably in either a sample or blank [Ref. 1, Section 1.1]. Since the sample analysis was not performed under the CLP, the MDL is used in place of the HRS-defined SQL [Ref. 1, Section 2.3].						
SGPP FACILITY OBSERVED RELEASE SAMPLE RESULTS – PFOA						
Field Sample ID	Laboratory Sample ID	Hazardous Substance	Date Sampled	Result (ng/L)	MDL** (ng/L)	Reference(s)
SGPP-MW02D	K1605066-006	PFOA	5/10/2016	18,000	14	22, p. 32; 23, p. 143; 55, pp. 9, 18
SGPP-MW03	K1605066-008	PFOA	5/11/2016	7,200	14	22, p. 33; 23, p. 143; 55, pp. 9, 20
SGPP-MW04	K1605066-009	PFOA	5/10/2016	2,100	5.4	22, p. 32; 23, p. 143; 55, pp. 9, 21
SGPP-MW05	K1605066-010	PFOA	5/11/2016	590	0.27	22, p. 33; 23, p. 143; 55, pp. 9, 22
SGPP-MW06*	K1605066-011	PFOA	5/11/2016	570	0.27	22, p. 33; 23, p. 144; 55, pp. 10, 23
ng/L = nanograms per liter MDL = method detection limit * environmental duplicate of SGPP-MW05 ** For HRS purposes, the DL used is the MDL, which is the lowest concentration of analyte that a method can detect reliably in either a sample or blank [Ref. 1, Section 1.1]. Since the sample analysis was not performed under the CLP, the MDL is used in place of the HRS-defined SQL [Ref. 1, Section 2.3]. <i>Notes on samples</i> <ul style="list-style-type: none"> • Release sample concentrations are compared to the most upgradient deep well sample concentration. • Sampling Methods: The background and release samples were all collected by EPA from monitoring wells installed by SGPP at the McCaffrey Street facility that are screened in the same hydrologic unit, using an EPA SOP, during the same sampling event in May 2016 [Figure 2; Ref. 7, pp. 200, 202–206, 208, 210–213; 22, pp. 31–33; 23, pp. 41–45, 48–51, 143–144; 30, pp. 46–50, 56–58]. • Analytical Procedures: The background and release samples were all analyzed for PFCs by a single EPA-subcontracted laboratory using standard operating procedures for extraction, analysis (high performance liquid chromatography/mass spectrometry), and quality control [Ref. 55, pp. 77, 80; 57, pp. 3, 10–18, 23]. The data were validated by EPA according to EPA Region 2 data validation guidelines [Ref. 58, pp. 1–22]. • The behavior and fate of PFCs in sandy aquifer sediment is affected by pore water pH, which impacts their adsorptive properties. As pH decreases the potential of PFCs to adsorb to aquifer sediment increases [Ref. 53, pp. 2, 7]. Background ground water sample SGPP-MW01D showed a higher pH than the release samples, suggesting that the PFOA exhibited greater mobility near the background well than near the release wells. 						

VILLAGE WELLS BACKGROUND SAMPLE RESULTS – PFOA						
Field Sample ID	Laboratory Sample ID	Hazardous Substance	Date Sampled	Result (ng/L)	MDL** (ng/L)	Reference(s)
SGPP-DW02	K1605268-002	PFOA	5/16/2016	140	0.27	22, p. 37; 23, p. 158; 56, pp. 9, 14
SGPP-DW04*	K1605268-004	PFOA	5/16/2016	150	0.27	22, p. 37; 23, p. 158; 56, pp. 9, 16
* Environmental duplicate of SGPP-DW02 ng/L = nanograms per liter MDL = method detection limit ** For HRS purposes, the DL used is the MDL, which is the lowest concentration of analyte that a method can detect reliably in either a sample or blank [Ref. 1, Section 1.1]. Since the sample analysis was not performed under the CLP, the MDL is used in place of the HRS-defined SQL [Ref. 1, Section 2.3].						
VILLAGE WELL OBSERVED RELEASE SAMPLE RESULTS – PFOA						
Field Sample ID	Laboratory Sample ID	Hazardous Substance	Date Sampled	Result (ng/L)	MDL* (ng/L)	Reference(s)
SGPP-DW01	K1605268-001	PFOA	5/16/2016	520	0.27	22, p. 37; 23, p. 158; 56, pp. 9, 13
ng/L = nanograms per liter MDL = method detection limit * For HRS purposes, the DL used is the MDL, which is the lowest concentration of analyte that a method can detect reliably in either a sample or blank [Ref. 1, Section 1.1]. Since the sample analysis was not performed under the CLP, the MDL is used in place of the HRS-defined SQL [Ref. 1, Section 2.3].						

That at least part of the significant increase in the release concentrations of PFOA, TCE and vinyl chloride is attributable to the SGPP site is documented on pages 45 to 48 of the HRS documentation record at proposal. In summary, the EPA showed that TCE and PFOA are associated with the Site sources, and vinyl chloride is a degradation product of TCE. In addition, the EPA documented that there are no known upgradient (in terms of ground water flow) alternative sources of these contaminants in the vicinity of the Site. Section 3.9.2, Observed Releases - Attribution, of this support document further discusses the attribution of vinyl chloride to the Site.

This comment results in no change to the HRS score and no change in the decision to place the Site on the NPL.

3.9.2 Observed Releases – Attribution

Comment: SGPP contested the attribution of the observed release of vinyl chloride to the Site specifically stating that attribution of the vinyl chloride in PSW 6 to alleged historic releases of TCE at Saint-Gobain Performance Plastics Corporation is flawed; the single detection of vinyl chloride at a concentration of 1.3 ppb in PSW 6 is attributable to low levels of TCE in ground water at the Site is not supported by the scientific data; the EPA has not presented sufficient evidence to support the degradation of TCE at the Site in MW-6 to the vinyl chloride detected in PSW 6; and the EPA's analysis of the migration of vinyl chloride in the aquifer is flawed and is inconsistent with claims made in the HRS documentation record at proposal.

SGPP commented that the EPA's assumption that the single detection of vinyl chloride at a concentration of 1.3 ppb in PSW 6 is attributable to low levels of TCE in ground water at the Site is not supported by the scientific data. It explained that although vinyl chloride is a breakdown product of TCE, the EPA has not presented any degradation rate calculations or other ground water data to adequately explain how the 13 ppb of TCE detected in MW-3 at the Site may be the source of the 1.3 ppb of vinyl chloride detected in PSW 6. It, thus, claimed that the available data suggest the contrary.

SGPP also commented that the EPA's explanation of the absence of TCE or vinyl chloride in any of the downgradient monitoring wells by theorizing that the vinyl chloride is 'traveling horizontally' in the upper aquifer

before being drawn down into the lower aquifer by the pumping of PSW 6 is unavailing (see page 47 of the HRS documentation record). SGPP contended that there is no data to support this assumption, and in fact, the EPA rejected the same theory when evaluating whether the vinyl chloride in PSW 6 might be attributable to the nearby laundromat, stating that the silt and clay layer that separated the upper and lower aquifers ‘would likely form a barrier to a solvent release.’ Additionally, contended SGPP, this theory fails to account for the fact that vinyl chloride has historically not been detected in the Village’s wells (SGPP Exhibits 1, 2, and 12).

SGPP commented that there is no basis to conclude that vinyl chloride in PSW 6 is attributable to conditions at the Site. SGPP made the following claims to support its comments:

- Vinyl chloride is not present in any monitoring well at the Site or any of the downgradient or off-site monitoring wells located between the Site and PSW 6 (References 23 and 35 of the HRS documentation record at proposal). Available ground water sampling data from the Site and the monitoring wells installed by the EPA between the Site and the Village wells demonstrate that the single detection of 1.33 ppb of vinyl chloride in PSW 6 is not attributable to releases at the Site. (References 23 and 35 of the HRS documentation record at proposal.)
- Vinyl chloride was not detected by the Village in any of its supply wells during its annual monitoring between 2004 and 2009, in 2011, or in 2014, as would be expected if the vinyl chloride detected by the EPA in 2016 were attributable to historic releases of TCE from past operations at the Site. (SGPP Exhibits 1, 2, 3, and 12.)⁶
- TCE was not detected by the EPA in any of the ground water monitoring wells located downgradient of MW-3 (including MW-4 and MW-5 at the Site and EPA offsite well GW-03 and GW-04). (References 23 and 35 of the HRS documentation record at proposal.)
- TCE was not detected by the EPA in any of the Village’s supply wells between 2004 and 2009, or in 2011, 2014, or 2015 (SGPP Exhibits 1-3, 12) (References 23 and 35 of the HRS documentation record at proposal). If TCE were migrating from the vicinity of MW-3 at the Site towards the Village’s wells, one would expect to find appreciable amounts of TCE downgradient from MW-3. Similarly, one would expect there to be some historic detections of TCE in the Village’s wells. The absence of such data undermines the EPA’s conclusion that the vinyl chloride in PSW 6 is associated with the low levels of TCE detected at the Site.

Response: The significant increase in the vinyl chloride concentration in well PSW 6 was correctly attributed to the SGPP site consistent with the HRS. In establishing attribution of a release of vinyl chloride to this Site, the EPA documented that there are parent substances of vinyl chloride associated with the Site sources and in observed releases attributable to the Site, which the commenter did not challenge. Further, the EPA documented that the conditions do not prevent the parent substances from degrading to the daughter substance vinyl chloride and that the substances could migrate to the location of well PSW 6. The EPA also documented that there is no evidence suggesting that the significant increase in vinyl chloride concentrations could have come from other sources in the vicinity of the Site.

The HRS does not establish specific requirements for establishing attribution. HRS Section 3.1.1, *Observed release*, which provides specific instructions for establishing the observed release to the aquifer, states:

Establish an observed release to an aquifer by demonstrating that the site has released a hazardous substance to the aquifer. Base this demonstration on either:

⁶Exhibit 1 of SGPP comment document is: Annual Drinking Water Quality Report for 2011, Village of Hoosick Falls. Exhibit 2 of SGPP comment document is: Annual Drinking Water Quality Report for 2014, Village of Hoosick Falls. Exhibit 3 of SGPP comment document is: Annual Drinking Water Quality Report for 2015, Village of Hoosick Falls. Exhibit 12 of SGPP comment document is: National drinking Water Database, Hoosick Falls (V) Pws – Troy, NY.

- Direct observation—a material that contains one or more hazardous substances has been deposited into or has been observed entering the aquifer.
- Chemical analysis—an analysis of ground water samples from the aquifer indicates that the concentration of hazardous substance(s) has increased significantly above the background concentration for the site (see section 2.3). **Some portion of the significant increase must be attributable to the site to establish the observed release**, except: when the source itself consists of a ground water plume with no identified source, no separate attribution is required. [Emphasis added].

HRS Section 2.3, *Likelihood of release*, presents the basic requirements for establishing an observed release including attribution to the site in relevant part, as follows:

Establish an observed release either by direct observation of the release of a hazardous substance into the media being evaluated (for example, surface water) or by chemical analysis of samples appropriate to the pathway being evaluated (see sections 3, 4, and 6). The minimum standard to establish an observed release by chemical analysis is analytical evidence of a hazardous substance in the media significantly above the background level. **Further, some portion of the release must be attributable to the site.** [Emphasis added].

The HRS documentation record at proposal clearly established attribution of the significant increase in vinyl chloride concentrations in well PSW 6 to the Site. First, on pages 23 to 26 of the HRS documentation record at proposal, the EPA established that the TCE and cis-1,2-DCE are associated with the source at the site. In addition, the EPA documented observed releases of TCE. These substances are parent substances for vinyl chloride, as documented below. In characterizing the contaminated soil source at the Site, section 2.4.1 of the HRS documentation record at proposal provides sampling analytical results documenting TCE, and cis-1,2-DCE in soil samples on Site.

Page 19 of the HRS documentation record at proposal documents that chlorinated solvents were found in source samples:

Analysis of soil and ground water samples collected as part of a May 1996 [Environmental Site Assessment] ESA prepared for a former facility occupant, Furon Company, reported the presence of TCE at an estimated concentration of 4.0 µg/kg at soil sample location MW-1M-0 and in ground water in two monitoring wells, MW-2M (13 µg/L) and MW-5M [6 µg/L (estimated) and duplicate result 7 µg/L (estimated)] [Ref. 40, pp. 36, 40, 42, 44]. The compound 1,2-DCE, which the Phase II noted is a breakdown product of TCE, was detected in MW-5M and its duplicate MW-15M at 2.0 µg/L each [Ref. 40, p. 42]. The Phase II ESA noted that the facility maintains floor drains and a sump, and concluded that the TCE source may be related to the facility sump pit [Ref. 40, p. 46].

In addition, pages 36 and 37 of the HRS documentation record at proposal document a significant increase in TCE associated with the Site. Page 36 documents the background level for TCE:

TABLE 10. BACKGROUND SAMPLE RESULTS – TCE						
Field Sample ID	CLP Sample ID	Hazardous Substance	Date Sampled	Result (µg/L)	RDL* (µg/L)	Reference(s)
SGPP-MW05	BD3E9	TCE	5/11/16	5.0 U	5.0	22, p. 33; 23, p. 133; 33, p. 8; 35, pp. 6–10, 50, 140; 47, pp. 5, 325
SGPP-MW06 (Duplicate of SGPP-MW05)	BD3F0	TCE	5/11/16	5.0 U	5.0	22, p. 33; 23, p. 133; 33, p. 8; 35, pp. 6–10, 58, 141; 47, pp. 5, 335

µg/L = micrograms per liter

RDL = reporting detection limit

U = The analyte was analyzed for, but was not detected at a level greater than or equal to the level of the adjusted CRQL for sample and method.

*The RDL for each result is the CRQL adjusted for sample and method [Ref. 33, p. 8]. Since the samples were analyzed through CLP, these adjusted CRQLs are used in place of the HRS-defined SQL [Ref. 1, Sections 1.1 and 2.3].

Contaminated Samples – TCE

On May 11, 2016, EPA collected ground water sample SGPP-MW03 from SGPP facility monitoring well MW-3. Analysis reported the presence of TCE at a concentration of 13 µg/L. This result is compared to the TCE results reported for designated background monitoring well, MW-5.

Page 37 of the HRS documentation record at proposal documents observed release levels of TCE:

TABLE 12. OBSERVED RELEASE SAMPLE RESULTS – TCE						
Field Sample ID	CLP Sample ID	Hazardous Substance	Date Sampled	Result (µg/L)	RDL* (µg/L)	Reference(s)
SGPP-MW03	BD3E7	TCE	5/11/2016	13	5.0	22, p. 33; 23, p. 134; 33, p. 8; 35, pp. 6–10, 36, 138; 47, pp. 4, 304

µg/L = micrograms per liter

RDL = reporting detection limit

*The RDL for each result is the CRQL adjusted for sample and method [Ref. 33, p. 8]. Since the samples were analyzed through CLP, these adjusted CRQLs are used in place of the HRS-defined SQL [Ref. 1, Sections 1.1 and 2.3].

Notes on samples

- Release sample concentration is compared to the maximum RDL for non-detect background samples.
- Sampling Methods: The background and release samples were all collected by EPA from monitoring wells installed by SGPP at the McCaffrey Street facility that are screened in the same hydrologic unit, using an EPA SOP, during the same sampling event in May 2016 [Figure 2; Ref. 7, pp. 204, 206, 211, 213; 22, pp. 31–33; 23, pp. 47–50, 133–134; 30, pp. 46–50, 56–58].

- Analytical Procedures: The background and release samples were all analyzed for Organic TAL VOC parameters via EPA CLP SOW SOM02.3 (low/medium concentration) by the same laboratory (Chemtech Consulting Group of Mountainside, New Jersey) [Ref. 23, pp. 1, 3-4, 133–134; 47, pp. 1, 304, 325]. The chemical analyses were coordinated through the EPA CLP; EPA validated the data according to EPA Region 2 data validation guidelines (SDG: BD3E5) [Ref. 35, pp. 1, 6–10].

In addition, the HRS documentation record at proposal identifies activities at the SGPP commonly associated with chlorinated solvents. Page 15 of the HRS documentation record at proposal identifies that historical facility operations related to the manufacture of circuit board laminates and electronics were conducted at the SGPP facility from the early 1960s to 1987 (i.e., approximately 26 years). Also as discussed on page 34 of the HRS documentation record at proposal, chlorinated solvents can be associated with the Site based on a March 1996 Phase I Environmental Site Assessment (ESA) prepared for a former site occupant, Allied Signal Fluorglas. This document indicates that past uses of the facility included activities related to circuit board and electronics manufacturing. Further, on pages 19, 36, 41 and 42 of the HRS documentation record at proposal TCE, cis-1,2-DCE and PFOA were also documented in ground water samples collected in monitoring wells located on the SGPP facility.

Second, on pages 18, 35, 46 and 47 of the HRS documentation record at proposal, a rationale for why vinyl chloride is a possible degradation product of TCE at this site was provided to document this degradation could occur. An explanation of the degradation process of TCE to vinyl chloride provided in the HRS documentation record at proposal explains on pages 18, 35 and 47 that subsurface microorganisms can degrade chlorinated solvents via a variety of chemical processes. “The most important process for the natural biodegradation of chlorinated solvents is reductive dechlorination” (see page 35 of the HRS documentation record at proposal and pages 15-17 of Reference 38 of the HRS documentation record at proposal). The discussion of the degradation of TCE to its daughter substances (cis-1,2-DCE and vinyl chloride) found in releases attributable to the Site is supported by Reference 38⁷ of the HRS documentation record at proposal. Page 16 of Reference 38 of the HRS documentation record at proposal illustrates the transformation of chlorinated ethenes, such as TCE, via reductive dechlorination. In general, reductive dechlorination occurs by sequential dechlorination from tetrachloroethylene (PCE) to TCE to DCE to vinyl chloride to ethene. Page 16 of Reference 38 of the HRS documentation record at proposal provides a figure illustrating this degradation:

⁷ Reference 38 of the HRS documentation record at proposal: EPA. Technical Protocol for Evaluating Natural Attenuation of Chlorinated Solvents in Ground Water (EPA/600/R-98/128 (excerpts). September 1998.

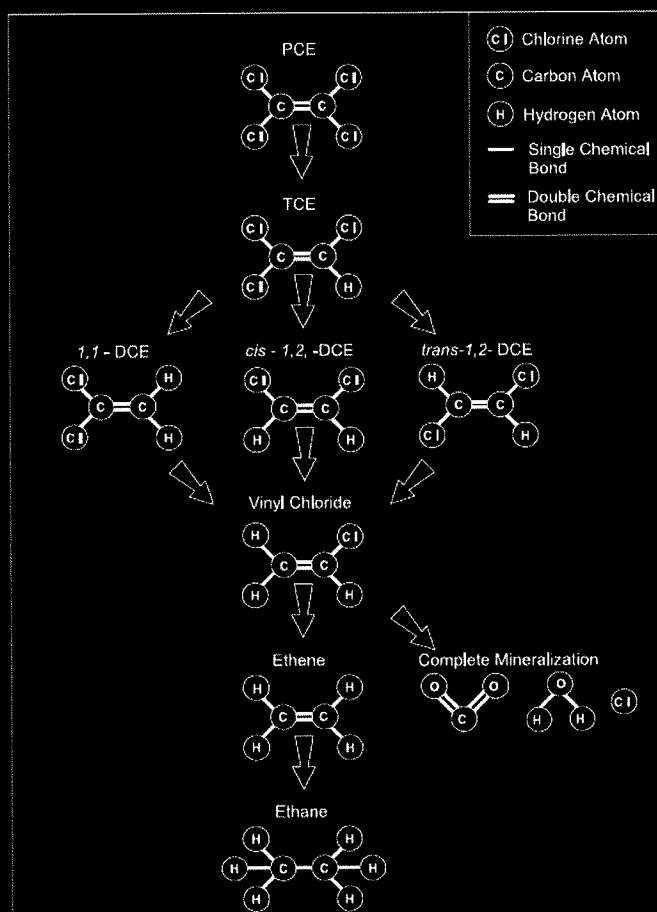


Figure 2.2 Reductive dehalogenation of chlorinated ethenes.

This information illustrates how TCE, detected in the source at the Site, can degrade to cis-1,2-DCE (also detected in a source at the Site) and vinyl chloride detected in a ground water observed release sample. This information is sufficient to attribute the release of solvents, including vinyl chloride to sources at the SGPP site. Further, SGPP has not provided evidence of another source of the chlorinated solvent including vinyl chloride documented at the Site.

Third, on pages 11 and 30 of the HRS documentation record at proposal the EPA identified that there is a possible migration pathway from the Site source to ground water. It did this by showing the geologic structure at the Site does not prevent contamination from migrating from the facility to the contaminated wells. Page 11 of the HRS documentation describes that the geologic features of the sand and gravel aquifer makes it conducive for contaminants to migrate from the sources to the wells.

Page 11 of the HRS documentation record at proposal states:

The municipal wells withdraw water from the lower sand and gravel aquifer that overlies bedrock [see Section 3.0.1 of this HRS documentation record]. The lower aquifer was deposited by glacial meltwater [Ref. 6, pp. 12–13, 17–18; 27, p. 3]. The deep gravel deposit is as much as 25 feet thick and is generally overlain by approximately 12 feet of fine sand that is part of the aquifer [Ref. 27, p. 3]. The areal extent of the sand and gravel aquifer is generally limited to the river valley areas, including the Hoosic River and its tributaries [Ref. 10, p. 1; 11, p. 21]. The lower aquifer is overlain by approximately 8 feet of poorly permeable clay and silt, which can be a barrier to water flow and separates the deep aquifer from the shallow aquifer [Ref. 6, pp. 12–13; 27, p. 3]. However, the lower aquifer is described as exhibiting “leaky artesian conditions” and there is evidence of site-attributable hazardous substance migration across the silt and clay layer; therefore, an aquifer interconnection occurs within 2 miles of sources at the site and, for Hazard Ranking System (HRS) scoring purposes, the upper and lower aquifers are evaluated together as a single hydrologic unit [Figure 3; see Section 3.1.1 of this HRS documentation record; Ref. 1, Section 3.0.1.2.1; 6, p. 18].

Page 30 of the HRS documentation record at proposal states:

The municipal wells withdraw water from the lower of two sand and gravel aquifers that overlie bedrock, as evidenced by available background information that indicates that Village Well 3, which has a total depth of 55 feet and a pump suction flange depth of 53 feet, withdraws water from the lower aquifer and that the total well depths and pump suction flange depths of Village Wells 6 and 7 are of similar or greater depth; therefore it is reasonable to conclude that Village Wells 6 and 7 also withdraw water from the lower aquifer [Ref. 27, pp. 7, 18; 28, pp. 1, 8, 13, 24–25, 27, 31, 37]...

The sand and gravel aquifer extends north of the well field along the valleys of the Hoosic River and its tributaries and underlies the SGPP facility [Ref. 10, p. 1]. Surficial deposits outside the valley areas consist primarily of glacial till, a heterogeneous mixture of grain sizes ranging from clay and silt to cobbles and boulders [Ref. 11, pp. 17, 20]. The thickness of the glacial till is variable and may exceed 100 feet; ground water yields are generally small and are considered sufficient for domestic use [Ref. 11, pp. 17, 20]....

...

The lower sand and gravel aquifer is described as exhibiting “leaky artesian conditions” [Ref. 6, p. 18]. In addition, the detection of VC in Village Well 6 documents that contamination has migrated between the upper and lower aquifers [see Section 3.1.1 of this HRS documentation record].

Pages 11 and 47 of the HRS documentation record at proposal also document that if there is a transport route from the Site source to the wells, the Site source would be within the radius of influence of the city wells, identifying that any ground water beneath the facility would be drawn to the city wells. Regarding the radius of influence of the city wells, the HRS documentation record states the following:

Page 11 of the HRS documentation record at proposal states:

[T]he pumping of the [V]illage wells has created a radius of influence that extends out as far as 0.67 mile and encompasses the SGPP facility [Ref. 7, pp. 22–23; 29, pp. 1–3; 42, p. 1]. Shallow

ground water flow beneath the SGPP facility is northwest to southeast toward the village wells [Ref. 7, pp. 22-23; 42, p. 1].

Page 47 of the HRS documentation record at proposal states:

EPA calculated the estimated radius of influence for the Village of Hoosick Falls water supply wells [Ref. 29, pp. 1–3]. Based on this calculation, the maximum radius of influence for the Village of Hoosick Falls water supply wells is estimated to be 3,530 feet (0.67 mile) [Ref. 29, pp. 2–3]. Based on this radius of influence, and the absence of VC in Village Wells 3 and 7, it is unlikely that any potential sources to the south, southeast, or southwest are contributing contamination to ground water beneath the SGPP facility or Village Well 6 [Ref. 43, pp. 28, 33, 49].

Fourth, pages 33 through 49 of the HRS documentation record at proposal present the EPA's rational for asserting that the significant increase in vinyl chloride or the parent substance TCE did not come from other sites. The background locations in ground water and soil samples screen out other upgradient and cross-gradient sources. Also, the EPA could not identify another site that used chlorinated solvents.

Regarding background wells location, page 34 of the HRS documentation record at proposal states:

SGPP facility monitoring well MW-5 is evaluated as representing background conditions. Based on the direction of ground water flow beneath the facility at the time of sampling, MW-5 is side-gradient to MW-3 [Figure 2; Ref. 7, pp. 20, 208, 210–213; 23, pp. 41–42, 44, 47, 49; 42, pp. 1, 6]. Analysis of ground water sample SGPP-MW05 and duplicate sample SGPP-MW06 reported non-detect values for TCE with an RDL of 5.0 µg/L [Ref. 22, p. 33; 23, p. 133; 33, p. 8; 35, pp. 2, 6–10, 50, 58, 140–141; 47, pp. 325, 335]. Ground water samples collected from SGPP facility monitoring wells MW-1 (Sample No SGPP-MW01D) and MW-2 (Sample No. SGPP-MW02D), which are situated upgradient of MW-3, reported non-detect values for TCE, documenting that the contamination has not migrated onto the SGPP facility from an upgradient off-site source to the north-northwest [Figure 2; Ref. 7, pp. 20, 200, 203, 208, 210; 22, p. 32–33; 23, pp. 41, 45, 48, 130, 134; 35, pp. 2, 6–10, 21, 29; 42, p. 1; 47, pp. 272, 294]. (Page 34 of the HRS documentation record at proposal)

Regarding the EPA investigation of other possible sources of solvents in the vicinity of the Site, page 47 of the HRS documentation record at proposal states:

EPA identified a laundromat located approximately 0.5 mile north-northeast of the SGPP facility [Ref. 44, pp. 1, 3, 6–7]. Information obtained from an employee indicates that dry cleaning has not been conducted historically or currently at the facility [Ref. 44, p. 2]. In addition, an extensive silt and clay layer (112 feet thick) was encountered during the April 2016 monitoring well installation activities approximately midway between the laundromat and the SGPP facility that would likely form a barrier to a solvent release from the laundromat or any other potential sources to the north-northeast [Ref. 44, pp. 1, 7–15]. In April 2016, EPA installed a monitoring well (EPA MW-5) at the intersection of Waterworks Road and Carey Avenue, east-northeast of the SGPP facility [Figure 3; Ref. 22, p. 14; 24, pp. 12–16]. The well is screened⁸ in the sand and gravel

⁸ EPA MW-5 is screened in the lower sand and gravel aquifer at an interval of 427.5 – 412.5 feet above mean sea level, the same relative elevations that MW-3 and PSW 6 are screened. MW-3 is screened at 432.33-417.33 feet above mean sea level; is located on the SGPP facility; and a release of TCE has been documented in MW-3. PSW 6 is screened at 380 feet above mean sea level, and a release of vinyl chloride is documented in PSW 6. (See pages 35, 36, 38 and Figure 3 of the HRS documentation record at proposal.)

aquifer beneath the silt and clay [Ref. 24, pp. 12–16]. Analysis of the ground water sample (SGPP-EPA-GW05) collected by EPA from this well reported a non-detect value for TCE, as well other chlorinated solvents [Ref. 43, pp. 2, 19–20; 44, p. 1; 48, pp. 383–384].

Regarding vinyl chloride not being detected in any monitoring wells at the Site, the rate of migration of vinyl chloride or degradation of parent substances to vinyl chloride in the aquifer could have influenced the lack of detection in these wells. Further, the HRS does not require multiple observed releases of a substance for a release of that substance to be eligible for evaluation. See section 3.9.1, Observed Releases-Applicable Standards, of this support document for discussion of observed release criteria. Also, regarding vinyl chloride not being detected in the Village supply wells during its annual monitoring between 2004 and 2009, in 2011, or in 2014, it is possible that the chlorinated solvent contamination had not yet migrated to those locations at concentrations above detection during those time periods. SGPP does not dispute that vinyl chloride has been found in PSW 6 in ground water sampling performed in 2015 and 2016. (See discussion above regarding 2016 sampling event documenting vinyl chloride in PSW6. See page 5 of Reference 8 of the HRS documentation record at proposal that includes a copy of The Village of Hoosick Falls *Annual Drinking Water Quality Report for 2015*⁹, which shows vinyl chloride being found in PSW 6 in sampling performed in 2015.)

Regarding TCE not being detected in monitoring wells located downgradient of MW-3 or in the Village supply wells during its annual monitoring between 2004 and 2009, in 2011, or in 2014, it is possible that this contamination had not yet migrated to those locations.

Regarding SGPP's claim that the EPA is theorizing that the vinyl chloride is 'traveling horizontally' in the upper aquifer before being drawn down into the lower aquifer by the pumping of PSW 6, finding of vinyl chloride in PSW 6 is sufficient evidence to document that there is some existing migration route, and vinyl chloride is not naturally occurring. This finding supports the conclusion that the clay layer present in the aquifer is not a barrier to migration of hazardous substances. Additionally, a cross section of subsurface geologic conditions included on pages 12 and 13 of Reference 6 of the HRS documentation record at proposal¹⁰ shows the silt and clay layer is not continuous in the aquifer between the SGPP facility and the location of well PSW-6.

These comments result in no change to the HRS score and no change in the decision to place the Site on the NPL.

3.10 Waste Characteristics

Comment: SGPP challenged the waste characteristics assigned value used to score the Site, stating that the waste characteristic value is inflated due to inaccurate hazardous waste quantity and a flawed PFOA toxicity factor value.

According to SGPP, the EPA assigned a hazardous waste quantity value of 100 to the ground water pathway and the maximum toxicity value of 10,000 to PFOA, which resulted in a total waste characteristic score of 32 for the ground water pathway. However, according to SGPP, both the ground water pathway hazardous waste quantity value of 100 and the toxicity value of 10,000 were not appropriate and therefore, the total waste characteristic value should not have been 32.

Response: The waste characteristic factor value, 32, assigned as part of the HRS scoring of the Site is consistent with HRS Sections 2.4, *Waste Characteristics*, (and its subsections), and 3.2, *Waste Characteristics* (and its subsections). As documented on page 49 of the HRS documentation record at proposal, both vinyl chloride and

⁹ The Village of Hoosick Falls *Annual Drinking Water Quality Report for 2015* is also available at: <http://www.villageofhoosickfalls.com/Media/PDF/WaterQualityReport2015.pdf>.

¹⁰ Reference 6 of the HRS documentation record at proposal: Hanson, Eric L., Dunn Geoscience Corporation. *Hydrogeologic Evaluation of the Hoosick Falls Aquifer*, Village of Hoosick Falls, New York. May 14, 1981.

PFOA were correctly assigned a toxicity factor value of 10,000 and a mobility value of 1 for HRS purposes, and when combined with the pathway hazardous waste quantity of 100, a waste characteristic factor value of 32 was appropriately assigned using HRS Table 2-7, *Waste Characteristics Factor Category Values*. Below is a summary of the specific factor values assigned and the calculated waste characteristics category value presented on page 49 of the HRS documentation record at proposal:

- Both vinyl chloride and PFOA are assigned a toxicity factor value of 10,000.
- Both vinyl chloride and PFOA are assigned mobility value of 1.
- The toxicity mobility value for vinyl chloride and for PFOA is: $10,000 \times 1 = 10,000$.
- The pathway hazardous waste quantity is assigned a value of 100¹¹
- Toxicity/mobility value \times pathway hazardous waste quantity:
 - $10,000 \times 100 = 1,000,000$ (or 1×10^6)

Based on the above assignments and using HRS Table 2-7, *Waste Characteristics Factor Category Values*, a waste characteristic product of 1×10^6 is assigned a waste characteristic factor value of 32, the value assigned in the HRS score at proposal (page 49 of the HRS documentation record at proposal).

SGPP's specific comments and the EPA's responses supporting the pathway hazardous waste quantity value and the PFOA toxicity factor value are discussed in the following sections:

- 3.10.1 Ground Water Pathway Hazardous Waste Quantity Value
- 3.10.2 PFOA Toxicity

3.10.1 Ground Water Pathway Hazardous Waste Quantity Value

Comment: SGPP commented that the EPA should not have assigned a pathway hazardous waste quantity of 100 to the ground water migration pathway.

SGPP stated that the EPA acknowledged the actual calculated hazardous waste quantity for the ground water pathway at the Site is 1, not 100, yet, "EPA assigned a hazardous waste quantity of 100 based on its conclusion that there are Level I and Level II Concentrations in target wells that may be attributed to the groundwater pathway." SGPP then explained that because the only Level I concentration present in any target wells is the 1.3 ppb of vinyl chloride that was detected in PSW 6 and vinyl chloride is not associated with or its release attributable to the Site, the hazardous waste quantity value assigned to the ground water pathway should have been 1, not 100, which, in turn, would have resulted in a lower total waste characteristic value.

Response: The ground water pathway hazardous waste quantity factor value of 100 was correctly assigned consistent with the HRS because the estimated pathway waste quantity was correctly based on a source waste quantity greater than zero but exact amount unknown; because the constituent waste quantity is not known with reasonable confidence; and, contrary to SGPP's assertions, because targets at the Site are subject to actual contamination at Level I and Level II concentrations.

HRS Section 3.2.2, *Hazardous waste quantity*, explains the assignment of the hazardous waste quantity for the ground water migration pathway. It states:

¹¹ The pathway waste quantity factor value was assigned consistent with HRS Sections 3.2.2, *Hazardous waste quantity*, and 2.4.2.2, *Calculation of hazardous waste quantity factor value*, and this documentation is shown on pages 27-28 and 49-52 of the HRS documentation record at proposal. See discussion below in section 3.10.1, Ground Water Pathway Hazardous Waste Quantity Value, of this support document.

Assign a hazardous waste quantity factor value for the ground water pathway (or aquifer) as specified in section 2.4.2. Enter this value in table 3-1.

HRS Section 2.4.2.2, *Calculation of hazardous waste quantity factor value*, explains the selection of the hazardous waste quantity factor value for a pathway considering all of the sources affecting that pathway: Sum the source hazardous waste quantity values assigned to all sources (including the unallocated source) or areas of observed contamination for the pathway being evaluated and round this sum to the nearest integer, except: if the sum is greater than 0, but less than 1, round it to 1. Based on this value, select a hazardous waste quantity factor value for the pathway from table 2-6.

TABLE 2-6—HAZARDOUS WASTE QUANTITY FACTOR VALUES

Hazardous waste quantity value	Assigned value
0	0
1 ^a to 100	1 ^b
Greater than 100 to 10,000	100
Greater than 10,000 to 1,000,000	10,000
Greater than 1,000,000	1,000,000

^a If the hazardous waste quantity value is greater than 0, but less than 1, round it to 1 as specified in text.

^b For the pathway, if hazardous constituent quantity is not adequately determined, assign a value as specified in text; do not assign the value of 1.

HRS Section 2.4.2.2, *Calculation of hazardous waste quantity factor value*, then provides additional instructions corresponding to footnote “b” of HRS Table 2-6 (in relevant part):

For a migration pathway, if the hazardous constituent quantity is adequately determined (see section 2.4.2.1.1) for all sources (or all portions of sources and releases remaining after a removal action), assign the value from table 2-6 as the hazardous waste quantity factor value for the pathway. **If the hazardous constituent quantity is not adequately determined** for one or more sources (or one or more portions of sources or releases remaining after a removal action) assign a factor value as follows:

- **If any target for that migration pathway is subject to Level I or Level II concentrations (see section 2.5), assign either the value from table 2-6 or a value of 100, whichever is greater, as the hazardous waste quantity factor value for that pathway.** [Emphasis added].

...

HRS Section 2.4.2.1.1, *Hazardous constituent quantity*, provides the conditions for when the hazardous waste quantity is adequately determined. It states, in relevant part:

If the hazardous constituent quantity for the source (or area of observed contamination) is adequately determined [that is the total mass of all CERCLA hazardous substances is known or estimated with reasonable confidence],...

Pages 19 through 29 of the HRS documentation record at proposal evaluated one source, Source 1, a contaminated soil source, at the Site. The EPA did not estimate the source hazardous constituent quantity because of the lack of sufficient information to do so, as explained on page 27 of the HRS documentation record at proposal:

The hazardous constituent quantity for Source 1 could not be adequately determined according to the HRS requirements; that is, the total mass of all Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) hazardous substances in the source and releases from the source is not known and cannot be estimated with reasonable confidence [Ref. 1, Section 2.4.2.1.1]. There are insufficient historical and current data [manifests, potentially responsible party (PRP) records, State records, permits, waste concentration data, etc.] available to adequately calculate the total or partial mass of all CERCLA hazardous substances in the source and the associated releases from the source. Therefore, there is insufficient information to evaluate the associated releases from the source to calculate the hazardous constituent quantity for Source 1 with reasonable confidence.

As directed in HRS Section 2.4.2, *Hazardous Waste Quantity*, and its subsections, when the hazardous constituent quantity, the hazardous wastestream quantity and the volume of the hazardous waste quantity are not known and could not be adequately estimated with reasonable confidence, the scoring of the hazardous waste quantity proceeds through Tiers A, B and C to Tier D, Area. On pages 27-28 of the HRS documentation record at proposal, the EPA documented a source waste quantity of greater than zero for Source 1 based on an area (Tier D) estimate using the instructions in HRS Section 2.4.2.1.4, *Area*. This HRS Section directs that the area value be based on the area of the source. The EPA explains on page 27 of the HRS documentation record at proposal that the area measure is appropriately assigned a value of >0:

Contaminated soil has been documented at the site; however, as contamination has been documented (e.g., SGPP-S07, SG1-MW04S-00.0) a definitive area of contamination has not been determined. Because the information available is insufficient to estimate the area and measure with reasonable confidence [as required in Section 2.4.2.1.4 of Reference 1], a value of greater than zero (>0) is established as the source hazardous waste quantity (HWQ) value for Tier D – area. The source type is "Contaminated Soil," so the area value is divided by 34,000 to obtain the assigned value of >0, as shown below [Ref. 1, p. 51591, Section 2.4.2.1.3, Table 2-5].

$$\begin{aligned}\text{Area of source in ft}^2 &= >0 \\ \text{Area (A) Assigned Value: } &>0/34,000 = >0\end{aligned}$$

The EPA notes that the commenter did not challenge this estimate.

On page 28 of the HRS documentation record at proposal, the EPA then documents the determination of the source waste quantity value as value greater than zero using the instructions in HRS Section 2.4.2.1.5, *Calculation of source hazardous waste quantity value*. This HRS Section directs the scorer to use the highest waste quantity estimate from any Tier. In this case, Tier D is the only tier scored and therefore the Tier D value was assigned as the source hazardous waste quantity value.

2.4.2.1.5 Source Hazardous Waste Quantity Value

The source hazardous waste quantity value for Source No. 1 is >0 for Tier D – Area [Ref. 1, p. 51591].

$$\text{Source Hazardous Waste Quantity Value: } >0$$

Page 49 of the HRS documentation record at proposal explains the sum of the source waste quantity, the application of HRS Section 2.4.2 and the assignment of a ground water pathway hazardous waste quantity of 100. It states on that page:

3.2.2 Hazardous Waste Quantity

TABLE 26. HAZARDOUS WASTE QUANTITY – GROUND WATER PATHWAY		
Source Number	Source Hazardous Waste Quantity (HWQ) Value (Section 2.4.2.1.5)	Is source hazardous constituent quantity data complete? (yes/no)
1	>0	No
Sum of Values:	1 (rounded to 1 as specified in HRS Section 2.4.2.2)	

Therefore, because the sum of the source waste quantity was greater than zero, the sum of the source waste quantity was rounded to 1 per the instructions in footnote “a” to HRS Table 2-6, *Hazardous Waste Quantity Factor Values*, quoted above.

Page 49 of the HRS documentation record at proposal further explains that as required in HRS Section 2.4.2.2, *Calculation of hazardous waste quantity factor value*, and in footnote “b” to HRS Table 2-6, *Hazardous Waste Quantity Factor Values*, quoted above, the EPA assigned the hazardous waste quantity factor value of 100:

The sum corresponds to a hazardous waste quantity factor value of 1 in Table 2-6 of the HRS [Ref. 1, p. 51591]. However, based on the fact that targets are subject to Level I and Level II concentrations (see Section 3.3.2.3), a hazardous waste quantity factor value of 100 is assigned if it is greater than the hazardous waste quantity value from Table 2-6 of the HRS (i.e., 1) [Ref. 1, pp 51591-51592]. Therefore, a hazardous waste quantity factor value of 100 is assigned for the ground water pathway [Ref. 1, pp 51591-51592].

Hazardous Waste Quantity Factor Value: 100

The HRS documentation record at proposal and at promulgation documented that targets are subject to vinyl chloride at Level I concentrations in PSW 6, and targets are subject to Level II concentrations of PFOA in PSW 7 (pages 50, 51 and 52 of the HRS documentation record at proposal and at promulgation). Either of the Level I or Level II concentrations in the target wells PSW 6 or PSW 7, respectively, would support the pathway hazardous waste quantity value assigned.

As discussed in section 3.11.1, Level I Concentrations, of this support document, the EPA correctly established both Level I and Level II targets at the Site based on vinyl chloride in an observed release at a level above an HRS benchmark and an observed release of PFOAs in drinking water wells, respectively, and assigned a pathway waste quantity of 100.

This comment results in no change to the HRS score and no change in the decision to place the Site on the NPL.

3.10.2 PFOA Toxicity

Comment: SGPP challenged the HRS toxicity factor value, 10,000, assigned to PFOA stating that the reference dose that is used as its basis is based on inappropriate assumptions. SGPP concluded that, ultimately, the EPA reference dose¹² for PFOA is not based upon sound scientific data or established regulatory principles; use of that reference dose to assign a toxicity value for the purpose of establishing a HRS score for the Site is fundamentally flawed; and use of a more appropriate regulatory toxicity value for PFOA would have resulted in a lower and more appropriate total waste characteristic value for the ground water pathway at the Site resulting in a lower HRS score.

¹² Reference dose (RfD). HRS Section 1.1, *Definitions*, defines an RfD as an, “[e]stimate of a daily exposure level of a substance to a human population below which adverse noncancer health effects are not anticipated. [milligrams toxicant per kilogram body weight per day (mg/kg-day)].”

Response: The EPA correctly assigned an HRS toxicity factor value of 10,000 to PFOA according to the directions contained in HRS Section 2.4.1.1, *Toxicity factor*, and HRS Table 2-4, *Toxicity Factor Evaluation*, based on its reference dose of 0.00002 mg/kg/day (or 2×10^{-5} mg/kg/day). This reference dose was obtained from *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)* (EPA, 2016) and was determined using sound scientific information and standard accepted procedures.

HRS Section 3.2.1.1, *Toxicity*, of the ground water migration pathway directs how to determine the correct toxicity factor value for specific substances for the ground water migration pathway. It states:

Assign a toxicity factor value to each hazardous substance as specified in Section 2.4.1.1.

HRS Section 2.4.1.1, *Toxicity factor*, states in relevant part:

Evaluate toxicity for those **hazardous substances at the site** that are available to the pathway being scored. For all pathways and threats, except the surface water environmental threat, **evaluate human toxicity** as specified below... [Emphasis added].

Establish human toxicity factor values based on quantitative dose-response parameters for the following three types of toxicity: [Emphasis added].

- Cancer-Use slope factors (also referred to as cancer potency factors) combined with weight-of-evidence ratings for carcinogenicity. If a slope factor is not available for a substance, use its ED₁₀ value to estimate a slope factor as follows:

$$\text{Slope factor} = \frac{1}{6(\text{ED}_{10})}$$

- Noncancer toxicological responses of chronic exposure-use reference dose (RfD) values.
- Noncancer toxicological responses of acute exposure-use acute toxicity parameters, such as the LD₅₀.

Assign human toxicity factor values to a hazardous substance using Table 2-4 as follows:

- **If RfD and slope factor values are both available for the hazardous substance, assign the substance a value from Table 2-4 for each. Select the higher of the two values assigned and use it as the overall toxicity factor value for the hazardous substance.** [Emphasis added].
- **If either an RfD or slope factor value is available, but not both, assign the hazardous substance an overall toxicity factor value from Table 2-4 based solely on the available value (RfD or slope factor).** [Emphasis added].
- If neither an RfD nor slope factor value is available, assign the hazardous substance an overall toxicity factor value from Table 2-4 based solely on acute toxicity. That is, consider acute toxicity in Table 2-4 only when both RfD and slope factor values are not available.
- If neither an RfD, nor slope factor, nor acute toxicity value is available, assign the hazardous substance an overall toxicity factor value of 0 and use other hazardous substances for which information is available in evaluating the pathway.

TABLE 2-4—TOXICITY FACTOR EVALUATION

Chronic Toxicity (Human)			
Reference dose (RfD) (mg/kg-day)		Assigned value	
RfD < 0.0005.....		10,000	
0.0005 ≤ RfD < 0.005		1,000	
0.005 ≤ RfD < 0.05		100	
0.05 ≤ RfD < 0.5		10	
0.5 ≤ RfD		1	
RfD not available		0	

Carcinogenicity (Human)			
Weight-of-evidence ^a /slope factor (mg/kg-day) ⁻¹			Assigned value
A	B	C	
0.5 ≤ SF ^b	5 ≤ SF	50 ≤ SF	10,000
0.05 ≤ SF < 0.5	0.5 ≤ SF < 5	5 ≤ SF < 50	1,000
SF < 0.05	0.05 ≤ SF < 0.5	0.5 ≤ SF < 5	100
- -	SF < 0.05	SF < 0.5	10
Slope factor not available	Slope factor not available	Slope factor not available	0
^a A, B, and C refer to weight-of-evidence categories. Assign substances with a weight-of-evidence category of D (inadequate evidence of carcinogenicity) or E (evidence of lack of carcinogenicity) a value of 0 for carcinogenicity. ^b SF = Slope factor.			

Page 49 of the HRS documentation record at proposal lists a human toxicity factor value of 10,000 for PFOA.

HRS Section 2.4.1.1, *Toxicity factor*, directs the use of the PFOA RfD in assigning a HRS human toxicity factor value. The PFOA RfD of 0.00002 mg/kg/day (or 2.0×10^{-5} mg/kg/day) is documented on page 22 of Reference 13, *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)* (EPA, 2016), of the HRS documentation record at proposal. When the PFOA RfD of 0.00002 mg/kg/day is applied to the “Chronic Toxicity (Human)” section of HRS Table 2-4, *Toxicity Factor Evaluation*, it falls in the category of “RfD < 0.0005” mg/kg/day and the assigned human toxicity factor value for that category is 10,000. Thus, the HRS documentation record at proposal and at promulgation correctly assigned a human toxicity factor value of 10,000 for PFOA based on an oral RfD of 0.00002 mg/kg/day (or 2.0×10^{-5} mg/kg/day). (See page 49 of HRS documentation record at proposal; page 22 of Reference 13¹³ of the HRS documentation record at proposal; pages 1-2 of Reference 34¹⁴ of the HRS documentation record at proposal.)

Regarding SGPP’s assertion that replacing the PFOA toxicity factor value with what they consider a more appropriate value would lower the HRS site score, this is not the case. Even if the PFOA HRS toxicity factor value of 10,000 was removed from the HRS documentation record, the Site score would not change because the toxicity and mobility values associated with vinyl chloride would continue to support the toxicity/mobility component of the waste characteristics factor category value component of the Site score. Vinyl chloride is correctly identified in an observed release to ground water from the Site as explained in section 3.9.1, Observed Releases-Applicable Standards, of this support document. This makes it eligible for inclusion in determining the

¹³ *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)* (EPA, 2016).

¹⁴ Snyder, Scott, WESTON. Project Note to Saint-Gobain Performance Plastics File, Subject: Toxicity and Mobility Factor Values for PFOA. June 8, 2016.

combined HRS toxicity/mobility factor value as directed in HRS Sections 3.2, *Waste characteristics*, and 3.2.1, *Toxicity /mobility*. The toxicity/mobility value for vinyl chloride is also 10,000 (see page 49 of the HRS documentation record at proposal), which the commenter did not challenge. Then, per HRS Section 3.2.1.3, *Calculation of Toxicity/mobility factor value*, the value assigned for the pathway scoring is the highest value for any substance associated with the pathway, and, thus, the value would be 10,000, which is the same value assigned at proposal. As no other HRS values would be impacted by lowering the PFOA toxicity, the Site score would, therefore, remain the same as at proposal.

The following subsections address SGPP's specific comments on the assigned PFOA human toxicity factor value and the adequacy of the studies used to develop the RfD used in this determination:

- 3.10.2.1 PFOA Reference Dose
- 3.10.2.2 PFOA Carcinogenicity
- 3.10.2.3 PFOA Human Epidemiology Studies

3.10.2.1 PFOA Reference Dose

Comment: SGPP stated that the reference dose identified for PFOA which is used to assign a toxicity factor value for this substance is based on inappropriate assumptions. SGPP's comments on the EPA methodology used to derive the PFOA reference dose are discussed in the following subsections:

- 3.10.2.1.1 Selection of Critical Effects
- 3.10.2.1.2 Use of Uncertainty Factors in Calculation of Reference Dose

3.10.2.1.1 Selection of Critical Effects

Comment: SGPP asserted that the PFOA RfD used in the assignment of an HRS human toxicity factor is premised on inappropriate assumptions that resulted in the improper selection of critical effects used in the RfD calculation.

SGPP claimed that the developmental effects upon which the reference dose is based (reduced ossification in the proximal phalanges of newborn mice and accelerated puberty in male mice pups) are transient developmental effects that do not alter the well-being of the mice (SGPP cited Exhibit 15¹⁵ of its comment document). SGPP added that the EPA authors of the study upon which the reference dose is based, state in the abstract of their report that 'no significant increase in malformations was noted in any treatment group' (SGPP cited to page 1 of Exhibit 16¹⁶ of its comment document). SGPP also commented that the same EPA authors did not identify either of these effects as adverse effects in their subsequent 2007 review paper in which they addressed the potential developmental toxicity of PFOA (SGPP cited Exhibit 17¹⁷ of its comment document.). Hence, SGPP commented that, "it is not clear why USEPA selected those endpoints as the critical effects from a protective regulatory policy perspective, for what it considered to be the 'most protective' endpoints in the most 'sensitive' population, from which it developed its reference dose for PFOA."

¹⁵Exhibit 15 of SGPP comment document (available at EPA docket ID: EPA-HQ-OLEM-2016-0434-0015) is: *Drinking Water Health Advisory for Perfluorooctanoic Acid (PFOA)* (EPA, 2016).

¹⁶ Exhibit 16 of SGPP comment document (available at EPA docket ID: EPA-HQ-OLEM-2016-0434-0015) is: Lau, Christopher, et. al. (2006). "Effects of Perfluorooctanoic Acid Exposure during Pregnancy in the Mouse", *Toxicological Sciences*, 90(2): 510-518.

¹⁷ Exhibit 17 of SGPP comment document (available at EPA docket ID: EPA-HQ-OLEM-2016-0434-0015) is: Lau, Christopher, et.al. (2007). "Review, Perfluoroalkyl Acids: A Review of Monitoring and Toxicological Findings", *Toxicological Sciences*, 99(2): 366-394.

SGPP also claimed that as well as the effects being transient, there are also “inconsistencies in the data from the experimental animal study that the reference dose is based upon, which calls into question whether there is any relationship between PFOA exposure and the purported developmental effects upon which the reference dose was derived.” SGPP explained that, for example, the reduction in ossification of forelimb and hind limb proximal phalanges observed in the Lau et al. (2006) study was greater at the lowest and highest doses, but statistically significant decreased proximal phalangeal ossification was not consistently observed in the mid-doses from the study as would be expected if the effect were actually related to PFOA exposure levels (SGPP Exhibit 16 at Table 2).

In addition, SGPP also raised issues with the effect of PFOA on sexual maturation in general. It stated that the sexual maturation data indicated that the greatest effect (an earlier attainment of sexual maturation by four days) occurred at the lowest PFOA dose, with the effect becoming less and approaching the control value as the dose increased, which is entirely inconsistent with what would be expected if the effect were caused by exposure to PFOA (SGPP Exhibit 16 at Table 5). Moreover, per SGPP, the sexual maturation data from Lau et al. (2006) was also inconsistent with other experimental animal studies involving PFOA that have reported that PFOA delays, rather than accelerates, sexual maturity in male rats (SGPP Exhibit 18¹⁸).

SGPP summarized that ultimately, the data from the Lau et al. (2006) study is highly suspect and should not have formed the basis for the derivation of a reference dose for PFOA.

Response: For HRS scoring purposes, the RfD used to assign PFOA a human toxicity factor value of 10,000 meet the HRS definition of an RfD. It was obtained from the EPA document titled, *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)* (EPA, 2016), which was subjected to a notice and comment period that closed on April 29, 2014. The EPA considers the studies supporting the PFOA RfD were correctly interpreted and used to assign an RfD. A summary of the studies and the derivation of the PFOA RfD is provided in the *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)* (EPA, 2016) document included as Reference 13 of the HRS documentation record at proposal. The adverse effects upon which the RfD for PFOA was derived are consistent with the EPA’s *Guidelines for Developmental Toxicity Risk Assessment* (EPA, 1991). The *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)* document and the RfD for PFOA derived within were subject to an extensive review process. Therefore, the use of the RfD from this study for PFOA was appropriate for use in the development of a human toxicity factor value, for HRS scoring purposes.

The following discussion is presented in the following order:

- HRS requirements for selection of an RfD
- Overview of the peer review process for the RfD
- Summary of the development process for the RfD
- Overview of the peer review charge questions
- Response to SGPP’s specific comments

Further, the EPA points out that even if the PFOA HRS toxicity factor value of 10,000, which was assigned based on its RfD, was removed from the HRS documentation record, the Site score would not change because the association of vinyl chloride with the Site would continue to support the toxicity/mobility component of the waste characteristics factor category value component of the Site score. (See section 3.10.2 of this support document for further explanation of this alternative scoring.)

HRS Requirements for Selection of an RfD

While HRS Section 1.1, *Definitions*, defines an RfD as an “[e]stimate of a daily exposure level of a substance to a human population below which adverse noncancer health effects are not anticipated. [milligrams toxicant per

¹⁸ Exhibit 18 of SGPP comment document is: Butenhoff, John L, et. al. (2004). “Characterization of Risk for General Population Exposure to Perfluorooctanoate”, *Regulatory Toxicology and Pharmacology*, 39: 363-380.

kilogram body weight per day (mg/kg-day)],” the HRS contains no directions on how to calculate this value or what would be an acceptable source of the RfDs.

The EPA selected the value from the most recent EPA study in which an RfD was calculated, the *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)* document. This document and specifically the derivation of the PFOA RfD by the EPA was subjected to a peer and public review. The notice for public comments was posted in the *Federal Register* on February 28, 2014 (<https://www.gpo.gov/fdsys/pkg/FR-2014-02-28/pdf/2014-04455.pdf>). The draft *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)* document was made available in the EPA docket at <http://www.regulations.gov> (Docket ID No. EPA-HQ-OW-2014-0138) and on an EPA contractor’s website (<http://peerreview.versar.com/epa/pfoa/>). The *Federal Register* notification requested nominations for peer reviewers and public comments. The nomination period for scientific experts began on February 28, 2014, and ended on March 21, 2014. The public comment period began on February 28, 2014, and ended on April 29, 2014. Thus, the RfD underwent a public notice and comment process before being issued. At this time, the EPA is not accepting additional comments as the study has been completed. The PFOA health assessment was initiated by the EPA Office of Water, Office of Science and Technology in 2009. The draft *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)* was completed in 2013 and released for public comment in February 2014. An external peer-review panel meeting was held on August 21 and 22, 2014. The final document reflects input from the panel as well as public comments received on the draft document. Both the peer-reviewed draft and the final document include only the sections of a health effects support document (HESD) that cover the toxicokinetics and health effects of PFOA. (See page 3 of Reference 13 of HRS documentation record at proposal, *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)* (EPA, 2016)).

Overview of the Peer Review Process for the RfD

The peer review covered technical issues through the use of independent experts. The information discussed in the peer review process formulated revisions to the draft document. The final document reflects sound technical information and analyses subjected to the peer review. This information is publicly available in the peer review summary. (See Appendix A: *EPA Response to External Peer Review Comments on EPA Draft Documents: Health Effects Support Document for Perfluorooctanoic Acid (PFOA) and Health Effects Support Document for Perfluorooctane Sulfonate (PFOS)* (May 2016) [herein referred to as *EPA Response to External Peer Review Comments*]).

In the August 2014 external peer review, the peer reviewers were asked to evaluate the scientific and technical merit of the draft document and provide their responses to 12 charge questions. This included evaluating the appropriateness of the quality, accuracy, and relevance of the data in the documents and included the studies, the selection of the studies and the procedures used in the assignment of the RfD. In addition to being provided the draft documents and charge questions, comments submitted to the EPA’s public docket (Docket ID number EPA–HQ–OW–2014–0138) during each document’s 60-day public comment period were provided to the peer reviewers ahead of the meeting for their consideration. Also, a brief summary of the public comments was provided to the reviewers. (See pages 4–6 of Appendix A: *EPA Response to External Peer Review Comments*.) The EPA responses to the peer reviewers address the peer reviewers’ general impression; the 12 charge questions topic areas; and editorial and other technical comments.

Summary of the Development Process for the RfD

The development of the RfD was consistent with accepted standard procedures set forth by the National Research Council and the EPA, and it was thoroughly peer reviewed. As stated on page 4 of Reference 13, *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)* (EPA, 2016), of the HRS documentation record at proposal, the studies included in the final *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)* were determined to provide the most current and comprehensive description of the toxicological properties of PFOA and the risk it poses to humans exposed to it in their drinking water. Appendix B of the final draft summarizes the studies evaluated for inclusion in the *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)* following the August 2014 peer review and identifies those selected for inclusion in the final assessment. Appendix B of the final draft includes epidemiology data that provide a high-level summary of the outcomes across the studies evaluated. (See page 4 of Reference 13 of the HRS documentation record at proposal.)

As stated on page 4 of Reference 13, *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)* (EPA, 2016), of the HRS documentation record at proposal, the development of the hazard identification and dose-response assessment for PFOA followed the general guidelines for risk assessment set forth by the National Research Council (1983) and EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (EPA, 2014). Other EPA guidelines used in the development of this assessment include the following:

- *Guidelines for the Health Risk Assessment of Chemical Mixtures* (EPA, 1986)
- *Guidelines for Mutagenicity Risk Assessment* (EPA, 1986)
- *Recommendations for and Documentation of Biological Values for Use in Risk Assessment* (EPA, 1988)
- *Guidelines for Developmental Toxicity Risk Assessment* (EPA, 1991)
- *Interim Policy for Particle Size and Limit Concentration Issues in Inhalation Toxicity Studies* (EPA, 1994)
- *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry* (EPA, 1994)
- *Use of the Benchmark Dose Approach in Health Risk Assessment* (EPA, 1995)
- *Guidelines for Reproductive Toxicity Risk Assessment* (EPA, 1996)
- *Guidelines for Neurotoxicity Risk Assessment* (EPA, 1998)
- *Science Policy Council Handbook: Peer Review (2nd edition)* (EPA, 2000)
- *Supplemental Guidance for Conducting Health Risk Assessment of Chemical Mixtures* (EPA, 2000)
- *A Review of the Reference Dose and Reference Concentration Processes* (EPA, 2002)¹⁹
- *Guidelines for Carcinogen Risk Assessment* (EPA, 2005)
- *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens* (EPA, 2005)
- *Science Policy Council Handbook: Peer Review (3rd edition)* (EPA, 2006)
- *A Framework for Assessing Health Risks of Environmental Exposures to Children* (EPA, 2006)
- *Exposure Factors Handbook* (EPA, 2011)
- *Benchmark Dose Technical Guidance Document* (EPA, 2012)
- *Child-Specific Exposure Scenarios Examples* (EPA, 2014)

In the process of developing the RfD, the EPA reviewed and presented numerous studies and several candidate RfDs. This RfD assessment was not isolated to just “a” single study showing adverse effects at low doses of PFOA. Rather, several studies document adverse effects at low doses of PFOA. From these studies, the summary of candidate RfDs presented in Table 4-9 of the *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)* (EPA, 2016) (Reference 13 of the HRS documentation record at proposal) were derived from several points of departure with differing critical effects, and the resulting candidate RfDs differ by about an order of magnitude (0.00002–0.00015 mg/kg/day) as do the uncertainty factor values applied to the points of departure.

¹⁹ See <https://www.epa.gov/sites/production/files/2014-12/documents/rfd-final.pdf>

From the candidate RfDs presented on page 255 of the *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)* (EPA, 2016), the EPA selected the RfD of 0.00002 mg/kg/day based on effects observed in a developmental toxicity study in mice for PFOA (Lau et al., 2006) and explained that the PFOA toxicity studies demonstrate that the developing fetus is particularly sensitive to PFOA-induced toxicity.

Page 255 of Reference 13, *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)* (EPA, 2016) of the HRS documentation record at proposal provides the candidate RfDs:

Table 4-9. The Impact of Quantification Approach on the RfD Outcomes for the HEDs from the PK Model Average Serum Values

POD	Value mg/kg/day	UF _H	UF _A	UF _L	UF _S	UF _D	UF _{total}	Candidate RfD mg/kg/day
PK-HED _{NOAEL} Perkins rats; ↑liver weight/necrosis	0.0044	10	3	-	-	-	30	0.00015
PK-HED _{LOAEL} Wolf GD 1-17 mice; ↓pup body weight	0.0109	10	3	10	-	-	300	0.00004
PK-HED _{LOAEL} Wolf GD 7-17 mice; ↓pup body weight ^a	0.0123	10	3	10	-	-	300	0.00004
PK-HED _{NOAEL} DeWitt mice; ↓IgM response to SRBC	0.0053	10	3	-	10	-	300	0.00002
PK-HED _{LOAEL} Lau mice reduced pup ossification (m, f), accelerated male puberty	0.0053	10	3	10	-	-	300	0.00002
PK-HED _{LOAEL} Butenhoff □ ↓F0 body weight/↑ absolute and relative kidney weight	0.0064	10	3	10	-	-	300	0.00002

Notes: m = male; f = female; SRBC = Sheep Red Blood Cell

^aserum from pups on PND²⁰ 22

As stated on page 22 of Reference 13, *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)* (EPA, 2016), of the HRS documentation record at proposal:

EPA used a peer-reviewed **PK [pharmacokinetic] model to calculate the average serum concentrations** associated with candidate no observed adverse effect levels (NOAELs) and lowest observed adverse effect levels (LOAELs) from six studies for multiple effects to calculate corresponding human equivalent doses (HEDs) for the derivation of candidate reference doses (RfDs). Overall, the **toxicity studies available for PFOA demonstrate that the developing fetus is particularly sensitive to PFOA-induced toxicity**. In addition to the critical developmental effects described above, other adverse effects include decreased survival, delays in eye opening and ossification, skeletal defects, delayed vaginal opening in females, and altered mammary gland development. [Emphasis added].

The EPA Office of Water (OW) **selected an RfD of 0.00002 mg/kg/day** based on effects observed in a developmental toxicity study in mice for PFOA (Lau et al. 2006). **The RfD is**

²⁰ PND = postnatal data

based on reduced ossification and accelerated puberty (in males). The total uncertainty factor (UF) applied to the HED LOAEL from Lau et al. (2006) is 300 and includes a UF of 10 for intrahuman variability, a UF of 3 to account for toxicodynamic differences between animals and humans, and a UF of 10 to account for use of a LOAEL as the point of departure (POD²¹). [Emphasis added].

Overview of the Peer Review Charge Questions

In the external panel review, the 12 charge questions posed to the peer reviewer panel addressed topic areas that include: 1. Studies used for quantification; 2. Additional references; 3. Use of epidemiological data; 4. Characterization of epidemiological data; 5. Cancer classifications; 6. Use of pharmacokinetic model; 7. Selected parameters of pharmacokinetic model; 8. Volume of distribution and half-life values; 9. Candidate RfD; 10. Duration; 11. Interspecies uncertainty factor; and 12. Other suggestions. Based on the reviewer panel comments, the EPA reanalyzed its assessment and included clearly defined adverse effects. The final assessment of the candidate RfDs include adverse effects identified in the animal studies such as increased liver weight accompanied by some necrosis, decreased pup body weight, decreased immunoglobulin response, reduced ossification in pups, accelerated puberty in male pups, and decrease in body weight accompanied by an increase in relative kidney weight. (See pages 254-255 of Reference 13, *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)* of the HRS documentation record at proposal; pages 7 and 8 of Appendix A: *EPA Response to External Peer Review Comments*.)

The selection of critical effects was addressed in charge question 9²² posed to external panel reviewers as well as in the peer reviewer general impressions comments. Based on peer reviewer panel comments that when identifying LOAELs that the EPA should select endpoints that represents a defined adverse effect, the EPA made some revisions to its assessment in the selection of adverse effects originally presented in the draft RfD document. Among the adverse effects selected as points of departure, the EPA included reduced ossification and accelerated puberty in male mice as critical effects and the LOAELs associated with these effects as appropriate points of departure for determining the final RfD supported in the *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)* document. These points of departure are also supported by several other candidate RfDs which together presented a narrow range of RfDs, 0.00002–0.00015 mg/kg/day. (See page 59 of Appendix A: *EPA Response to External Peer Review Comments*; see Table 4-9 on page 255 of Reference 13, *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)*, of the HRS documentation record at proposal, cited above.) The selection of the reduced ossification and accelerated puberty in male mice as critical effects (and the human equivalent dose derived from these endpoints as the points of departure to derive the RfD) are intended to be protective of the human population including sensitive subpopulations, which in this case are the developing fetus and newborn. (See pages 59 -62 of Appendix A: *EPA Response to External Peer Review Comments*.) Deriving an RfD from a dose that presents significant adverse or overt toxicity as a point of departure would not be protective of human health.

²¹ Point of departure (POD): “The dose-response point that marks the beginning of a low-dose extrapolation. This point can be the lower bound on dose for an estimated incidence or a change in response level from a dose-response model (BMD), or a NOAEL or LOAEL for an observed incidence, or change in level of response.” *A Review of the Reference Dose and Reference Concentration Processes* (EPA, 2002). <https://www.epa.gov/sites/production/files/2014-12/documents/rfd-final.pdf>

²² Charge Question 9 - Candidate RfDs: A variety of endpoints and studies were used to compare points of departure and the resultant RfDs for both PFOA and PFOS. In addition, comparisons were provided across RfD outcomes based on the model outputs compared to those for the NOAEL, LOAEL and BMDL points of departure. The range of candidate RfDs derived from the different points of departure is fairly narrow. Please comment on the strengths, weaknesses and transparency of this analysis.

The duration of studies as it impacts assessing short term and long term exposures and their association with diverse effects, are addressed in charge question 10²³ posed to the external panel reviewers. Based on peer reviewer panel comments, the EPA revised the selection of critical effects presented in the draft RfD document and included among its selection reduced ossification and accelerated puberty in male mice because the RfD should be protective against adverse developmental effects on the developing fetus and offspring resulting from exposures that occur during gestation. "Because the developing organism is changing rapidly and is vulnerable at a number of various stages in development, a single exposure at a critical time in development can produce an adverse effect (USEPA 1991)." (See page 63 of Appendix A: *EPA Response to External Peer Review Comments*.)

The use of a pharmacokinetic (PK) model to derive the human equivalent dose is addressed in charge questions 6²⁴, 7²⁵, and 8²⁶ posed to the external panel reviewers. (See pages 45-58 of *EPA Response to External Peer Review Comments*.) In addressing their comments, the EPA agreed that further refinement of the model will eventually be ideal when the state of the science permits it. However, the model is empirical and has shown to give results that agree with observed data. The EPA noted in its response, "A unique feature of the Wambaugh et al. (2013) approach was to use a single model for all species in the toxicological studies to examine the consistency in the average serum values associated with effects and with no effects from nine animal studies of PFOA." (See page 47 of the Appendix A: *EPA Response to External Peer Review Comments*.) The panel reviewers noted in their comments that the August 2014 face to-face peer review meeting had extensive discussion regarding modeling and whether the clarifications of Dr. Wambaugh, who was also present at that meeting, were adequate. In response to the discussions and the panel reviewer comments, the EPA also clarified in the final *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)* that a single PK model was used to reanalyze all available data, and "[t]he tables containing the new PK parameter estimates have been retitled 'Pharmacokinetic parameters from Wambaugh et al. (2013) meta-analysis of literature data' to further indicate that this reanalysis occurred." (See page 49 of Appendix A: *EPA Response to External Peer Review Comments*; page 72 of Reference 13, *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)*, of the HRS documentation record at proposal.)

Hence, the *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)* and the *EPA Response to External Peer Review Comments* provide sufficient technical justification for the acceptability of the RfD for HRS purposes.

²³ Charge Question 10 - Duration: The RfDs for PFOS and PFOA are derived from the modeled steady state serum concentrations and their association with effects that include short term and longer term exposures with associated diverse effects. The studies considered included effects due to exposure durations that ranged from 11 to 182 days and occur at comparable human equivalent dose (HED) levels. The current draft RfDs do not include an uncertainty factor for study duration because of the apparent concordance HEDs despite duration differences. Given this pattern of response, is it appropriate to conclude that the candidate RfDs are applicable to both short-term and lifetime exposures?

²⁴ Charge Question 6 - Use of Pharmacokinetic Model: Significant interspecies differences in pharmacokinetics exist for both PFOA and PFOS. Adjusting for interspecies differences was an important step in developing candidate RfDs given the totality of the human and animal data. Please comment on the strengths and weaknesses of the pharmacokinetic model adjustments to accommodate the impact of albumin binding and renal tubule transporters in determining average serum values.

²⁵ Charge Question 7 - Selected Parameters of Pharmacokinetic Model: Table 5-5 in the PFOA document and Table 5-7 in PFOS document list the parameters used for the ORD pharmacokinetic models that provide the final serum and AUC values for calculating the internal dose point of departure for the RfD calculation. Please comment on the strengths and weaknesses of the selected parameters.

²⁶ Charge Question 8 - Volume of Distribution and Half-life Values: The volume of distribution (Vd) and half-life values are critical in the derivation of the interspecies uncertainty factor applied in derivation of candidate RfDs from a NOAEL, LOAEL or a BMDL. The available data for both values are provided in Section 3.5.2 and 3.5.3 of both documents. Please comment the strengths and weaknesses of the values selected.

Response to SGPP's Specific Comments

The EPA considers the studies supporting the PFOA RfD acceptable and has provided a summary of the studies and the derivation of the PFOA RfD in the *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)* (EPA, 2016) document included as Reference 13 of the HRS documentation record at proposal. Responses to SGPP's comments that the PFOA reference dose is premised on inappropriate assumptions are as follows:

First, regarding two of SGPP's claims: (1) that developmental effects upon which the RfD is based (reduced ossification and accelerated puberty in male mice pups) are transient developmental effects that do not alter the well-being of the mice, and (2) why the EPA selected those endpoints as the critical effects from a protective regulatory policy perspective, for what it considered to be the 'most protective' endpoints in the most 'sensitive' population, from which it developed its reference dose for PFOA, the evaluation of reduced ossification as well as accelerated puberty as critical effects (i.e., adverse effects) is consistent with standard developmental toxicity assessment procedures as presented in the EPA *Guidelines for Developmental Toxicity Risk Assessment* (EPA, 1991)²⁷. Page 4 of this document states:

The four major manifestations of developmental toxicity are death, structural abnormality, altered growth, and functional deficit. The relationship among these manifestations may vary with increasing dose and, especially at higher doses, death of the conceptus may preclude expression of other manifestations. Of these, all four manifestations have been evaluated in human studies, but only the first three are traditionally measured in laboratory animals using the conventional developmental toxicity (also called teratogenicity or Segment II) testing protocol as well as in other study protocols, such as the multigeneration study or the continuous breeding study.

Thus, consistent with the EPA *Guidelines for Developmental Toxicity Risk Assessment*, the Lau et al. (2006) study correctly identified reduced ossification as a critical developmental toxicity effect or endpoint. (See Section 3.1.1.2, Endpoints of Developmental Toxicity: Altered Survival, Growth, and Morphological Development, and Section 3.1.1.4, Overall Evaluation of Maternal and Developmental Toxicity, of EPA's *Guidelines for Developmental Toxicity Risk Assessment* (EPA, 1991).) In the *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)*, the EPA further explains that the developmental studies are important in quantification of dose-response because the exposures occur during critical windows of development and predicate effects that can occur later in life (page 244 of Reference 13 of the HRS documentation record at proposal).

Second, regarding SGPP's claim that authors of the study upon which the reference dose is based, state in the abstract of their report that "no significant increase in malformations was noted in any treatment group", this statement has been presented out of context by the commenter. It must be read within context of the results summarized for all the treatment groups in the study. The authors, did *not* state that no malformations were observed, only that there was no significant increase in one group than in another. At the 1 mg/kg dose and other doses, the study documented an increase in malformations over the control. That is, in assessing the **number of ossified proximal phalanges** (forelimbs and hindlimbs) impacted at the 1 mg/kg/day dosing level, Table 2 of the Lau et al. (2006) study document that the **control exhibited** 4.8 ± 0.8 sites for ossified forelimbs and 3.9 ± 0.9 ossified hindlimbs. **In contrast, the 1 mg/kg PFOA dose group exhibited** 1.8 ± 1.0 sites for ossified forelimbs and 0.4 ± 0.3 ossified hindlimbs. This marked reduction in the number of ossified proximal phalanges (forelimbs and hindlimbs) was noted by the authors who indicated that these results show significant differences ($p < 0.05$) from controls, meaning that there is a less than 0.05 probability that these results are inaccurate. Similarly, the data also showed that the percent of reduced ossification for other skeletal sites were also markedly increased over control. Table 2 of the Lau et al. (2006) study reports these findings as shown below.

²⁷ <https://cfpub.epa.gov/ncea/risk/recorddisplay.cfm?deid=23162>

Table 2 of Lau et al. (2006) study:

Table 2 Mouse Reproductive Outcome and Fetal Teratology, Examined at Term							
	PFOA dosage (mg/kg)						
	0	1	3	5	10	20	40
Dams examined (#)	45	17	17	27	26	42	9
Dams with FLR (#)	3	2	1	7	12	37	9
Dams with FLR (%)	6.7	11.8	5.9	25.9*	46.1*	88.1*	100*
Implants (# per litter with FLR)	7.0 ± 4.0	10.0 ± 3.0	13.0	11.6 ± 1.2	10.8 ± 1.2	11.5 ± 0.6	11.9 ± 0.5
Implants (# per live litter)	12.9 ± 0.4	13.1 ± 0.4	11.6 ± 0.9	11.5 ± 0.5	12.6 ± 0.6	10.2 ± 2.1	—
Live fetuses (# per live litter)	12.5 ± 0.4	13.0 ± 0.4	10.8 ± 0.9	11.1 ± 0.4	11.7 ± 0.8	7.2 ± 2.0*	—
Prenatal loss (% per live litter)	4.1 ± 1.4	1.0 ± 0.7	7.4 ± 2.5	2.4 ± 0.8	7.7 ± 3.3	25.9 ± 11.7*	—
Fetal body weight (g)	1.05 ± 0.02	0.98 ± 0.03	1.03 ± 0.04	1.03 ± 0.04	0.98 ± 0.05	0.86 ± 0.11*	—
Notable skeletal findings (n)	13	6	7	11	5	5	—
Ossification (number of sites):							
Sternebrae	5.9 ± 0.1	6.0 ± 0.1	6.0 ± 0.1	5.5 ± 0.3	5.7 ± 0.2	4.0 ± 1.1*	—
Caudal vertebrae	4.3 ± 0.3	4.1 ± 0.1	4.0 ± 0.2	4.3 ± 0.3	3.7 ± 0.2	2.1 ± 0.7*	—
Metacarpals	7.7 ± 0.2	7.3 ± 0.3	7.6 ± 0.2	6.6 ± 0.5	6.8 ± 0.4	5.2 ± 1.4*	—
Metatarsals	9.3 ± 0.3	8.9 ± 0.4	9.1 ± 0.3	8.2 ± 0.6	8.6 ± 0.4	6.2 ± 1.6*	—
Proximal phalanges (forelimb)	4.8 ± 0.8	1.8 ± 1.0*	2.2 ± 0.9*	2.9 ± 0.9	1.0 ± 0.6*	0.0 ± 0.0*	—
Proximal phalanges (hindlimb)	3.9 ± 0.9	0.4 ± 0.3*	1.5 ± 1.0	2.8 ± 0.9	1.0 ± 0.6*	0.0 ± 0.0*	—
Reduced ossification(%):							
Calvaria	13.5 ± 9.2	62.5 ± 15.5*	66.7 ± 13.0*	22.7 ± 10.4	35.0 ± 12.7	55.0 ± 20.0*	—
Supraoccipital	14.7 ± 4.0	33.3 ± 10.5	28.6 ± 8.5	27.3 ± 9.2	45.0 ± 9.4*	90.0 ± 10.0*	—
Unossified hyoid	0	0	0	0	0	26.7 ± 19.4*	—
Enlarged fontanel	17.3 ± 9.1	66.7 ± 21.1*	53.6 ± 15.8*	18.2 ± 9.6	45.0 ± 20.0	95.0 ± 5.0*	—
Notable visceral findings (n)	10	6	6	11	5	5	—
Tail defects (curly, bent) (%)	0	0	0	20.5 ± 5.7*	5.0 ± 5.0*	11.7 ± 7.3*	—
Limb defects (club, bent) (%)	0	0	0	5.7 ± 2.8*	0	5.8 ± 3.9*	—
Microcardia (%)	0	0	0	0	5.0 ± 5.0*	30.0 ± 18.3*	—
<i>Note.</i> Data represent means ± SE of litters examined as indicated. One-way ANOVA indicates significant differences ($p < 0.05$) in number of live fetuses and prenatal loss. Asterisks denote significant differences from controls ($p < 0.05$) by Fisher's exact test for full litter resorptions (FLR) and by Dunnett's t-test for other parameters.							

Hence, while the authors did state no significant increase in malformations was detected in the lower PFOA dose groups, they did not conclude that no adverse effects were observed at the 1 mg/kg dose level. Further, in selecting a lowest concentration corresponding to an observed adverse effect level as a point of departure (a dose-response point that marks the beginning of a low-dose extrapolation) to base the RfD on, a level corresponding to

significant overt toxicity would not be protective of human population including sensitive subpopulations, which in this case are the developing fetus and newborn.

The abstract of the Lau et al. (2006) study states:

Perfluorooctanoic acid (PFOA), a member of the perfluoroalkyl acids that have wide commercial applications, has recently been detected in humans and wildlife. The current study characterizes the developmental toxicity of PFOA in the mouse. **Timed pregnant CD-1 mice were given 1, 3, 5, 10, 20, or 40 mg/kg PFOA** by oral gavage daily from gestational day (GD) 1 to 17; controls received an equivalent volume (10 ml/kg) of water. PFOA treatment produced dose-dependent full-litter resorptions²⁸; all dams in the 40-mg/kg group resorbed their litters. Weight gain in dams²⁹ that carried pregnancy to term was significantly lower in the 20-mg/kg group. At GD 18, some dams were sacrificed for maternal and fetal examinations (group A), and the rest were treated once more with PFOA and allowed to give birth (group B). Postnatal survival, growth, and development of the offspring were monitored. PFOA induced enlarged liver in group A dams at all dosages, but did not alter the number of implantations. The percent of live fetuses was lower only in the 20-mg/kg group (74 vs. 94% in controls), and fetal weight was also significantly lower in this group. However, **no significant** increase in malformations was noted in any treatment group. The incidence of live birth in group B mice was significantly lowered by PFOA: ca. 70% for the 10- and 20-mg/kg groups compared to 96% for controls. Postnatal survival was severely compromised at 10 or 20 mg/kg, and moderately so at 5 mg/kg. Dose-dependent growth deficits were detected in all PFOA treated litters except the 1-mg/kg group. Significant delays in eye-opening (up to 2–3 days) were noted at 5 mg/kg and higher dosages. Accelerated sexual maturation was observed in male offspring, but not in females. **These data indicate maternal and developmental toxicity of PFOA in the mouse, leading to early pregnancy loss, compromised postnatal survival, delays in general growth and development, and sex-specific alterations in pubertal maturation.** [Emphasis added].

In the discussion of the Lau et al. (2006) study, the authors stated:

In contrast, the onset of puberty for the male pups was markedly advanced by PFOA, such that the prepuce³⁰ was separable in the **1-mg/kg dose** group almost 4 days earlier than in the controls. It is noteworthy that this accelerated pubertal maturation took place despite a body weight deficit of 25–30%. [Emphasis added].

...

Teratological³¹ findings (such as reduced ossification) typically reflected delays of fetal development, although a few incidences of malformed limbs and tail, and microcardia were detected at 5 mg/kg and higher dose groups. On the other hand, the BMD₅ **estimates for phalangeal ossification were less than 1 mg/kg (Table 6)**³², indicating the sensitivity of this PFOA effect. **That reduced ossification was observed at such low doses without affecting**

²⁸ Resorption is early pregnancy loss; early embryonic or fetal death.

²⁹ Dams referred to here are the female parent mice.

³⁰ Genitalia

³¹ Teratological - abnormal in growth or structure; of or relating to teratology.

Teratology-the study of malformations or deviations from the normal types in developing organisms.

³² The EPA notes that Table 6, *Benchmark Dose Estimates for Various Parameters of PFOA, Maternal and Developmental Toxicity in the Mouse*, of the Lau et al. (2006) study contains the BMD₅ and BMDL₅ extrapolated from the administered dose. However, Table 2, *Mouse Reproductive Outcome and Fetal Teratology, Examined at Term*, of the Lau et al. (2006) study contains the administered dose. The lowest administered dose showing reduced ossification is Table 2 of the Lau et al. (2006) study is 1 mg/kg.

fetal weight suggests the possibility that effects on ossification may not be a simple developmental delay. Regardless, these findings are generally comparable to those reported for two related PFAA chemicals, perfluorodecanoic acid (Harris and Birnbaum, 1989) and PFOS (Thibodeaux et al., 2003). [Emphasis added].

The Lau et al. (2007) study where it states, ‘no significant increase in malformations was noted in any treatment group’, the authors stated the following:

Accordingly, Lau et al. (2006) carried out a reproductive toxicity study with PFOA in CD-1 mice using daily **doses of 1–40 mg/kg throughout gestation**. Full-litter resorptions were noted at 40 mg/kg. At 20 mg/kg, the percent of live fetuses and fetal weight were reduced and some structural abnormalities were seen in the fetuses. However, no **significant** increase in malformations was detected in the lower PFOA dose groups. The lack of significant teratological findings in mice was consistent with previous studies using rats and rabbits (Gortner, 1981, 1982; Staples et al., 1984). However, when neonatal survival was evaluated in this study, a pattern of neonatal mortality mirroring that obtained with PFOS (Lau et al., 2003) was observed. Postnatal survival was severely compromised at 10 or 20 mg/kg and moderately affected at 5 mg/kg. **Postnatal growth impairment and developmental delays were noted among the survivors in these same dose groups.** [Emphasis added].

Third, regarding SGPP’s claim that the authors did not identify either reduced ossification or accelerated puberty in male mice as adverse effects in their subsequent 2007 review paper in which they addressed the potential developmental toxicity of PFOA, the Lau et al. (2006) and Lau et al. (2007) studies do not actually refute each other. The Lau et al. (2007) study is not a dosing study but is a review of previous literature of perfluoroalkyl acids and does not include all the detailed observations documented in the Lau et al. (2006) study at the various doses of PFOA administered to mice. The Lau et al. (2006) study characterized developmental toxicity of PFOA in pregnant mice and provides detailed dosing and responses observed at the various dosing levels (1–40 mg/kg), whereas the Lau et al. (2007) study is a review of the monitoring and toxicological findings of perfluoroalkyl acids (including PFOA). In addition in the Lau et al. (2007) study, the authors specifically noted that, “[t]his review provides an **overview** of the recent advances in the toxicology and mode of action for PFAAs³³, and of the monitoring data now available for the environment, wildlife, and humans. Several avenues of research are proposed that would further our understanding of this class of compounds” [emphasis added].

Fourth, regarding SGPP’s claim that there are inconsistencies in the data and that reduced ossification was greater at the lowest and highest doses but a statistically significant decrease was not observed at the mid-doses from the study, insufficient information is provided to assess these results. However, there are a number of factors such as differences in pharmacokinetic handling of PFOA in the mice and immature pups that can influence the observed adverse effects. Regardless, the conclusion that there was an adverse effect from the doses is not in doubt.

Fifth, regarding SGPP’s claim that the sexual maturation data are entirely inconsistent with what would be expected of exposure to PFOA as well as with the results of other experimental animal studies involving PFOA shown in SGPP Exhibit 18³⁴, these data do not show inconsistency but rather show that pharmacokinetics differences between species and even within species during development impact the adverse effect outcomes. The data in Table 2 of Exhibit 18 of SGPP’s comment document that SGPP referred to as being contradictory is from a study performed on rats, not mice as was used in the Lau et al (2006) study. These differences were noted in the Lau et al. (2006) study of which an excerpt is provided below.

³³ PFAA= perfluoroalkyl acids

³⁴ Exhibit 18 of SGPP comment document (available at EPA docket ID: EPA-HQ-OLEM-2016-0434-0015) is: Butenhoff et al. (2004). “Characterization of risk for general population exposure to perfluorooctanoate,” *Regulatory Toxicology and Pharmacology*. 39 (2004) 363–380.

Lau et al. (2006) states:

Results from the current study that evaluated the **developmental toxicity of PFOA in the CD-1 mouse are strikingly different than those described previously with the rat model.** Butenhoff et al. (2004b) conducted a comprehensive two generation reproductive toxicity study on PFOA with Sprague- Dawley rats and reported little toxicity; small postnatal weight gain deficits, **slight delays of sexual maturation**, and postweaning mortality (likely related to immaturity) were noted only in the F1-generation animals of the highest dose group (30 mg/kg). **In contrast, here we report** a significant increase in the incidence of full-litter resorptions and neonatal mortality in the CD-1 mouse at 5 mg/kg (Table 2), with BMD₅ and BMDL₅ estimated at 2.84 mg/kg and 1.09 mg/kg, respectively for neonatal mortality (determined by survival to weaning) (Table 6). **Significant alterations of postnatal growth and development were seen at even lower doses** (1 and 3 mg/kg, Fig. 5), with BMD₅ and BMDL₅ estimates of 1.07 mg/kg and 0.86 mg/kg respectively, for pup weight at weaning, and 2.64 mg/kg and 2.10 mg/kg respectively, for eye-opening (Table 6). **These disparate findings in rats and mice are likely due, at least in part, to the differential pharmacokinetic disposition of PFOA.** [Emphasis added].

Table 2 of Exhibit 18 of SGPP comment document shows the result in question (when compared to the Lau et al. (2006) study which used mice) is based on a study performed using rats (see emphasized text):

Table 2 Endpoints and source studies used in evaluating dose-response		
Endpoint	Source study	Source data table
Post-natal development in rats^a	Two-generation reproduction study (Butenhoff et al., 2004)	Table 3
Liver-to-brain-weight ratio in rats ^b	Two-generation reproduction study (Butenhoff et al., 2004)	Table 3
Body-weight change in rats ^c	Two-generation reproduction study (Butenhoff et al., 2004)	Table 3
Liver-to-brain-weight ratio in rats ^d	13-week dietary study (Palazzolo, 1993)	Table 4
Body-weight change	13-week dietary study (Palazzolo, 1993)	Table 4
Liver-to-brain-weight ratio in monkeys ^e	6-month oral toxicity study (Butenhoff et al., 2002b)	Table 5
Body-weight change in monkeys ^f	6-month oral toxicity study (Butenhoff et al., 2002b)	Table 5
Leydig cell tumors in rats ^g	Two-year cancer bioassay (Sibinski et al., 1983)	Table 6

^a The following endpoints were evaluated separately: (1) pre-weaning mortality (combined sexes); (2) pup body-weight at weaning (combined sexes); (3) post-weaning mortality in males and females (separately); (4) days to preputial separation in males; and (5) days to vaginal patency in females.

^b Male liver-weight-to-brain-weight ratio was selected because male rats respond to a greater extent than females to the liver-enlarging effects of PFOA. PFOA affects body weight; therefore, use of liver-weight-to-brain-weight ratio normalizes for body-weight changes, since brain is not responsive to body-weight change from dietary restriction (Feron et al., 1973). F₀ and F₁ data were evaluated separately. The two-generation reproduction study involved oral dosing of male rats in both the F₀ and F₁ generations for more than 90 days, the typical term of a subchronic study, and, therefore, has the advantage of following a subchronic dosing response over two generations and group sizes of approximately 30.

^c Body-weight change was evaluated as reduced body-weight gain compared to controls only in male rats, which were more sensitive than female rats to PFOA-induced reductions in weight gain. F₀ and F₁ data were evaluated separately.

^d Liver-weight-to-brain-weight ratio was used to minimize effects of body-weight reduction and reduced feed consumption. The 13-week (90-day) subchronic dietary study in male rats (Palazzolo, 1993) is useful in that serum PFOA concentrations were made at all dose levels.

^e Since the male monkeys from this study varied in age and weight at the beginning of the study, and dosing with APFO caused significant weight loss among the high-dose-group monkeys, only data from male monkeys dosed until terminal sacrifice were used, which excludes data from three high-dose-group monkeys for whom dosing was suspended.

^f For male cynomolgus monkeys, body-weight change was represented by the actual percentage change in individual body weight from pre-study baseline weight through weight at or near termination (scheduled or unscheduled) of dosing. Because these were adult monkeys of various ages and weights, and due to the fact that only two of six monkeys were dosed continuously for six months at the high dose, percent change in body weight from baseline was considered more meaningful than comparison of body-weight change or terminal body weight between treated and control groups.

^g Human epidemiological studies have not shown statistically significant associations of exposure to PFOA with increased cancer mortality risk (Alexander, 2001). Leydig cell adenoma incidence from the two-year cancer bioassay in rats was used.

These comments result in no change to the HRS score and no change in the decision to place the Site on the NPL.

3.10.2.1.2 Use of Uncertainty Factors in Calculation of Reference Dose

Comment: SGPP questioned the use of uncertainty factors of 10 and 3 used by the EPA in deriving the RfD. SGPP claimed that the EPA incorporated an inappropriate uncertainty factor³⁵ of 10 into its derivation of the reference dose used in the assignment of an HRS toxicity factor because the EPA used the lowest observed adverse effect level (LOAEL) as the point of departure (POD)³⁶ from which the RfD is based instead of the benchmark dose for a 5 percent response (BMDL₅)³⁷ calculated by the authors in the Lau et al. (2006) study. SGPP explained that the EPA's flawed RfD was based on the following calculations: the serum PFOA concentration associated with the LOAEL was estimated (38 mg/L), and a human equivalency dose was derived by multiplying this serum PFOA concentration by the estimated human clearance for PFOA (0.00014 L/kg/day), and this resulted in a human equivalent dose (HED) of 0.0053 mg/kg/day (SGPP Exhibit 15).

SGPP contended that in deriving the reference dose, the EPA used the LOAEL, 1 mg/kg/day, for the two co-critical effects as a point of departure in its reference dose calculations (SGPP Ex. 15 at Table 5-1.), and that because a LOAEL for the co-critical effects was used instead of a no observable adverse effect Level (NOAEL) or benchmark dose, the EPA added an uncertainty factor of 10 into its calculations to account for adverse effects that might theoretically occur at concentrations below the LOAEL (Table 5-2 of SGPP Exhibit 15). However, according to SGPP, in the Lau et al. (2006) study, the authors did derive benchmark doses for the reduced ossification of proximal phalanges (Table 6 of SGPP Exhibit 16 (the Lau et al. (2006) study)). SGPP stated:

³⁵ Uncertainty factor value (UF): "One of several, generally 10-fold, factors used in operationally deriving the RfD and RfC from experimental data. UFs are intended to account for (1) the variation in sensitivity among the members of the human population (i.e., interhuman or intraspecies variability); (2) the uncertainty in extrapolating animal data to humans (i.e., interspecies variability); (3) the uncertainty in extrapolating from data obtained in a study with less-than-lifetime exposure to lifetime exposure (i.e., extrapolating from subchronic to chronic exposure); (4) the uncertainty in extrapolating from a LOAEL rather than from a NOAEL; and (5) the uncertainty associated with extrapolation from animal data when the database is incomplete." *A Review of the Reference Dose and Reference Concentration Processes* (EPA, 2002).

³⁶ Point of departure (POD): "The dose-response point that marks the beginning of a low-dose extrapolation. This point can be the lower bound on dose for an estimated incidence or a change in response level from a dose-response model (BMD), or a NOAEL or LOAEL for an observed incidence, or change in level of response." *A Review of the Reference Dose and Reference Concentration Processes* (EPA 2002). <https://www.epa.gov/sites/production/files/2014-12/documents/rfd-final.pdf>.

³⁷ "Benchmark Dose (BMD) or Concentration (BMC): A dose or concentration that produces a predetermined change in response rate of an adverse effect (called the benchmark response or BMR) compared to background." ... "BMDL or BMCL: A statistical lower confidence limit on the dose or concentration at the BMD or BMC, respectively." *A Review of the Reference Dose and Reference Concentration Processes* (EPA, 2002). <https://www.epa.gov/sites/production/files/2014-12/documents/rfd-final.pdf>

For reduced ossification of the proximal phalanges for the forelimb and hind limb, the lower 95 percent confidence limits of the benchmark doses for a 5 percent response (BMDL₅) were 0.643 and 0.616 mg/kg/day, respectively. ([SGPP Exhibit 16, Table 6]) While these values are slightly lower than the LOAEL of 1 mg/kg used by USEPA, if USEPA had used the BMDL₅ for reduced proximal phalangeal ossification, it would not have needed to add in any uncertainty factor to account for potential effects below the LOAEL, let alone an uncertainty factor of 10. Accordingly, the dose ultimately used to derive the reference dose would have been 30 to 40 percent lower (BMDL₅ values of 0.646 or 0.616 versus the LOAEL of 1 mg/kg); but, the total uncertainty factor would have been 30 instead of 300, which would have resulted in a higher reference dose.

SGPP also commented that the EPA also applied an additional uncertainty factor of 3 to account for species differences between humans and mice even though there are experimental data that suggests that humans are less sensitive to the developmental effects observed in mice rather than more sensitive as the application of this uncertainty factor implies (SGPP Exhibit 19³⁸).

Response: For HRS scoring purposes, the RfD used to assign PFOA a human toxicity factor value of 10,000 met all HRS requirements. The use of uncertainty factor value of 10 in deriving the RfD was appropriate and standard procedure when the reported LOAEL is used instead of a level causing NOAEL because the NOAEL has not been established. In addition, in peer review of the EPA study containing RfD derivation, the reviewers did not question the use of this uncertainty factor of 10. The EPA did not apply the portion of the uncertainty factor for interspecies variability (UF_A) that accounts for toxicokinetic differences because the PK modeling accounted for that difference, but the EPA did retain the portion of that uncertainty factor that accounts for the differences in toxicodynamics between species (i.e., a UF_A value of 3 for the differences in the way PFOA interacts with tissues in animals versus in humans).

As explained in greater detail in section 3.10.2.1.1, Selection of Critical Effects, of this support document, the RfD was obtained from the EPA document titled, *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)*, (EPA, 2016), which was subject to a notice and comment process that closed on April 29, 2014. The EPA considers the studies supporting the PFOA RfD and the use of uncertainty factor values to derive the RfD appropriate and consistent with standard procedures; the use of the uncertainty factors accounts for limitations and uncertainties in the available data, when arriving at an RfD that is likely to be without an appreciable risk of deleterious effects in humans. The EPA has provided a summary of the studies and the derivation of the PFOA RfD in the *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)* (EPA, 2016) document included as Reference 13 of the HRS documentation record at proposal.

Further, as also explained in section 3.10, Waste Characteristics, of this support document, even if the PFOA HRS toxicity factor value of 10,000 was removed from the HRS documentation record, the Site score would not change because vinyl chloride would continue to support the toxicity/mobility component of the waste characteristics factor category value component of the Site score.

The application of the uncertainty factor of 10 to account for a LOAEL to NOAEL extrapolation was appropriate because the point of departure (POD) for the derivation of the RfD for PFOA is the human equivalent dose (HED), which was derived based on serum concentrations corresponding to a lowest observed adverse effect level.

³⁸ Exhibit 19 of SGPP comment document is: Albrecht, Prajakta P. et al. (2012). "A Species Difference in the Peroxisome Proliferator-Activated Receptor α -Dependent Response to the Developmental Effects of Perfluorooctanoic Acid", *Toxicological Sciences*, 131(2): 568-582.

Section 4.1.1, RfD determination, of Reference 13, *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)* of the HRS documentation record at proposal provides a detailed summary of the derivation of the RfD for PFOA. The introduction to this section, on page 241, explaining the RfD derivation provides the following statement that explains the need to utilize a pharmacokinetic (PK) model in the dose response assessment:

The derivation of the RfD for PFOA presented a number of challenges due to the toxicokinetic complexity of PFOA, variability in half-life between species, and metabolic inertness of PFOA in living organisms. The toxicokinetic features of PFOA lead to differences in half-lives across species and in the case of rats, and possibly humans, differences between genders. Toxicokinetics also influence intraindividual and lifestage variability in response to dose. Additionally there were inconsistencies across the epidemiology studies and the effects observed in animal studies, and a number of animal studies lacked a NOAEL. Each of these factors highlights the importance of having measures of internal dose for quantification of an RfD and supports the utilization of a PK model as a component of the dose-response assessment.

Section 4.1.2, RfD Selection, of Reference 13, *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)*, of the HRS documentation record at proposal explains the selection of the RfD among the candidate studies discussed in that document. It states on pages 256 and 257:

The candidate RfDs in Table 4-9 range 0.00002–0.00015 mg/kg/day. **The RfD of 0.00002 mg/kg/day calculated from HED [human equivalent dose] average serum values from Lau et al. (2006) was selected.** The RfD based on Lau et al. (2006) is derived from reduced ossification of the proximal phalanges (forelimb and hindlimb) and accelerated puberty in male pups (4 days earlier than controls) as the critical effects. The selected RfD from the Lau et al. study (2006) is supported by the RfD for effects on the response of the immune system (DeWitt et al. 2008) to external challenges as observed following the short-term 15-day exposures to mature mice and effects on organ and body weights in F1 adult males observed following chronic exposure. [Emphasis added].

...

Using the PK model of Wambaugh et al. (2013), **average serum PFOA** concentrations were derived from area under the curve (AUC) considering the number of days of exposure before sacrifice. **The predicted serum concentrations were converted** as described above **to oral HEDs in mg/kg/day** for each corresponding serum measurement. **The POD for the derivation of the RfD for PFOA is the HED of 0.0053 mg/kg/day that corresponds to a LOAEL that represents approximately 60% of steady-state concentration.** An UF of 300 (**10 UF_H, 3 UF_A, and 10 UF_L**)³⁹ was applied to the HED LOAEL to derive an RfD of 0.00002 mg/kg/day. [Emphasis added].

The application of uncertainty factor values applied in the range of RfD determinations are explained on pages 255 to 256 of Reference 13, *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)* (EPA, 2016), of the HRS documentation record at proposal which states:

A UF for interspecies variability (UF_A) of three was applied to account for uncertainty in extrapolating from laboratory animals to humans (i.e., interspecies variability). The 3-fold factor is applied to account **for toxicodynamic differences** between the animals and humans. The

³⁹ UF = uncertainty factor. UF_A = uncertainty factor to account for interspecies variability. UF_L = uncertainty factor for extrapolations beginning from a LOAEL. UF_H = uncertainty factor value to account for intraspecies variability (within the human populations variability). SGGP did not challenge the UF_H value applied.

HEDs were derived using average serum values from a model to account for PK differences between animals and humans. [Emphasis added].

A UF for LOAEL to NOAEL extrapolation (UF_L) of 10 was applied to all PODs other than the Perkins et al. study (2004) to account for use of a LOAEL for the POD. The POD for the Perkins et al. study (2004) is a NOAEL. [Emphasis added].

Therefore, because the human equivalent dose was derived from *serum levels corresponding to a LOAEL*, the application of the uncertainty of 10 for LOAEL to NOAEL extrapolation (UF_L) was appropriate. The EPA found it necessary to utilize PFOA serum concentrations available in the animal studies because the complexity of toxicokinetics of PFOA between species supported the utilization of a pharmacokinetic model utilizing serum concentrations corresponding to an administered dose. The use of the animal data and the available pharmacokinetic model allowed for the incorporation of species differences in saturable renal resorption, dosing duration, and serum measurements for doses administered to determine human equivalent doses based on average serum concentration and clearance. Pharmacokinetic modeling is a more rigorous approach to determining dosing for an adverse health effect than the BMDL₅, which is itself a calculation based on the NOAEL or LOAEL. Thus it would be inappropriate to use a BMDL₅ in a pharmacokinetic model.

Further, regarding SGPP's comment that, humans are less sensitive to the developmental effects observed in mice rather than more sensitive as the application of the uncertainty a factor value of 3 implies and regarding SGPP's citation to Exhibit 19 of its comment document, the EPA applied the uncertainty factor value of 3 for interspecies variability to account for differences in how PFOA interacts with tissues in animals versus in humans. The EPA did not apply the portion of the uncertainty factor for interspecies variability that accounts for toxicokinetic differences because the PK modeling accounted for that difference, but the EPA did retain the portion of that uncertainty factor that accounts for the differences in toxicodynamics between species.

Although the reference that SGPP cited (SGPP Exhibit 19⁴⁰) did perform a study on peroxisome proliferator-activated receptor (PPAR α)⁴¹ humanized mice as well as PPAR α -null mice and wild type mice to determine if species differences in receptor activity might influence the developmental effects induced by PFOA, this study made several observations, among which is that the developmental postnatal effects resulting from prenatal PFOA exposure in mice are differentially mediated by mouse and human PPAR α . It also noted that further studies are needed to identify the specific mechanisms accounting for species differences in responses to PFOA exposure. Additionally, the EPA noted the effect of the PPAR pathway in its assessment of PFOA (and discussed it in several areas throughout the PFOA health effects assessment document). The EPA stated on page 22 of Reference 13, *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)* (EPA, 2016), of the HRS documentation record at proposal:

PFOA is known to activate PPAR pathways by increasing transcription of mitochondrial and peroxisomal lipid metabolism, sterol, and bile acid biosynthesis and retinol metabolism genes. **Based on PFOA-induced transcriptional activation of many other genes in PPAR α -null mice, however, other receptors** such as the constitutive androstane receptor (CAR), farnesoid receptor (FXR), and pregnane X receptor (PXR) **could be involved in PFOA-induced toxicity.** [Emphasis added].

Therefore, the application of an uncertainty factor value of 3 to account for interspecies variability when deriving an RfD is appropriate. The results of the study in Exhibit 19 of SGPP's comment document are not sufficient to

⁴⁰ Exhibit 19 of SGPP comment document is: Albrecht, Prajakta P. et al. (2013). "A Species Difference in the Peroxisome Proliferator-Activated Receptor α -Dependent Response to the Developmental Effects of Perfluorooctanoic Acid", *Toxicological Sciences*, 131(2): 568-582.

⁴¹ Peroxisome proliferator-activated receptor α (PPAR α). PFOA binds to the PPAR α .

show that interspecies mechanisms mediating PFOA toxicity are sufficiently known to eliminate the need for the application of an uncertainty factor to account for the differences in how PFOA interacts with tissues in animals versus in humans.

Peer Review Charge Questions and the Use of Uncertainty Factors

The application of uncertainty factor values was addressed by the external peer review panel in their general comments as well as their comments on charge questions 8⁴², 9⁴³ and 11⁴⁴. A panel reviewer noted in his general comments that by adhering to the EPA policies and use of multiple uncertainty factor values, despite the scientifically-credible exercises and deliberations, the end result (the RfD) seems to have been preordained to be extremely low. The EPA addressed this comment as it impacted the selection of the endpoints in the final assessment and provided a response to the use of uncertainty factor values in its response to charge question 11, which is discussed below. (See pages 8 and 68-70 Appendix A: *EPA Response to External Peer Review Comments*.) For charge questions 8 and 9, direct comments against applying an uncertainty factor of 10 to extrapolations derived from a lowest observed adverse effect level were not provided, but rather, peer reviewer comments and the EPA responses and revisions to the proposed RfD addressed the pharmacokinetic model and selection of critical endpoints for the RfD. In responding to charge question 8, a peer reviewer did recommend that the EPA could use Bayesian analysis to support uncertainty factor value development. However, the EPA noted that “[since] there are no agreed upon guidelines for the new approach recommended by the peer reviewer, EPA used the current Agency approach for determining uncertainty factors in the PFOA assessment.” (See page 55 of Appendix A: *EPA Response to External Peer Review Comments*.) Another peer reviewer responding to charge question 8 also requested that the EPA provide a justification for using the uncertainty factor value of 3 to account for species differences and a more thorough discussion regarding this choice given the differences in clearance rates between humans and animals. In responding to this comment, the EPA made revisions to clearance ratios used in the PK model approach but retained the use of the uncertainty factor of 3 and explained:

In cases where the POD for RfD quantification is the product of toxicokinetic modeling, the toxicokinetic portion of the interspecies UF is not applied. In the absence of data regarding toxicodynamic differences between species, the toxicodynamic portion of the UF is retained. The toxicodynamic factor accounts for differences in the way the chemical interacts with tissues in the animals versus humans. The UF applied to account for toxicodynamics in such circumstances is 3 (see section 4.4.5.3 in EPA’s document *A Review of the Reference Dose Reference Concentrations Processes*). (See page 55 of Appendix A: *EPA Response to External Peer Review Comments*.)

⁴² Charge Question 8 - Volume of Distribution and Half-life Values: The volume of distribution (Vd) and half-life values are critical in the derivation of the interspecies uncertainty factor applied in derivation of candidate RfDs from a NOAEL, LOAEL or a BMDL. The available data for both values are provided in Section 3.5.2 and 3.5.3 of both documents. Please comment the strengths and weaknesses of the values selected.

⁴³ Charge Question 9 - Candidate RfDs: A variety of endpoints and studies were used to compare points of departure and the resultant RfDs for both PFOA and PFOS. In addition, comparisons were provided across RfD outcomes based on the model outputs compared to those for the NOAEL, LOAEL and BMDL points of departure. The range of candidate RfDs derived from the different points of departure is fairly narrow. Please comment on the strengths, weaknesses and transparency of this analysis.

⁴⁴ Charge Question 11 - Interspecies Uncertainty Factor: In addition to using the average serum values from animal studies to calculate internal doses for humans, the animal to human extrapolation can be accomplished by dividing animal average serum values by the human to animal clearance ratios to project a human average serum point of departure in units of mg/L serum. Please provide recommendations for applying uncertainty factors to the extrapolated average human serum values to determine serum-based thresholds that are protective for humans. A NOAEL expressed in average human serum units would be useful in interpreting NHANES population monitoring data.
NHANES = National Health and Nutrition Examination Survey

Hence, the EPA did not apply the portion of the uncertainty factor for interspecies variability (UF_A) that accounts for toxicokinetic differences because the PK modeling accounted for that difference, but the EPA did retain the portion of that uncertainty factor that accounts for the differences in toxicodynamics between species (i.e., a UF_A value of 3 for the differences in the way PFOA interacts with tissues in animals versus in humans).

For charge question 11, although the panel reviewers commented that use of human data would negate the need to perform animal to human extrapolations, no comments were provided against applying an uncertainty factor of 10 to extrapolations derived from a LOAEL or 3 for interspecies variability. In responding, the EPA noted the use of human equivalent doses derived from the modeled average serum value for the lowest observed adverse effect level (LOAEL) (and/or no observed adverse effect level (NOAELs) in some candidate RfD studies), pharmacokinetically-derived human equivalent doses based from the animal studies, interspecies differences between animals and humans and the application of the EPA policies in deriving reference dose justified the use of uncertainty factor values. (See pages 54 -55 and 68-70 of Appendix A: *EPA Response to External Peer Review Comments*).

This comment results in no change to the HRS score and no change in the decision to place the Site on the NPL.

3.10.2.2 PFOA Carcinogenicity

Comment: SGPP asserted that the EPA should not have assigned an HRS toxicity factor value of 10,000 to PFOA. SGPP commented that despite having studied the health effects of PFOA for decades, the EPA has not found adequate evidence to assign a regulatory classification to PFOA as a likely carcinogen. SGPP added that in the absence of such evidence, there is no reasonable basis to apply the same maximum toxicity factor that is applied to known carcinogens to PFOA.

Response: The HRS human toxicity factor value of 10,000 was not assigned based on the carcinogenicity of PFOAs, but, rather, was correctly based on the RfD as it resulted in the assignment of the highest factor value possible. As assigned at proposal and explained in section 3.10.2, PFOA Toxicity, of this support document, the HRS instructs if both an RfD and a cancer slope are available, assign the substance a toxicity factor value from HRS Table 2-4, *Toxicity Factor Evaluation*, for each and use the higher of the two values assigned as the overall toxicity factor value. As explained in sections 3.10.2, PFOA Toxicity, and 3.10.2.1, PFOA Reference Dose, of this support document, the HRS toxicity factor value of 10,000 was correctly assigned to PFOA according to the directions of HRS Section 2.4.1.1, *Toxicity factor*, and HRS Table 2-4, *Toxicity Factor Evaluation*, which explain the assignment of an HRS toxicity factor value of 10,000 to PFOA based on its RfD of 0.00002 mg/kg/day (or 2×10^{-5} mg/kg/day). The exclusion or inclusion of a cancer assessment or cancer slope factor does not negate the non-cancer toxicological parameter (RfD, in this case) used to assign a human HRS toxicity factor value for PFOA or the assignment of the 10,000 value.

HRS Section 3.2.1.1, *Toxicity*, of the ground water migration pathway states:

Assign a toxicity factor value to each hazardous substance as specified in section 2.4.1.1.

HRS Section 2.4.1.1, *Toxicity factor*, states:

Evaluate toxicity for those hazardous substances at the site that are available to the pathway being scored. For all pathways and threats, except the surface water environmental threat, evaluate human toxicity as specified below. ...

Establish human toxicity factor values based on quantitative dose-response parameters for the following **three types of toxicity**: [Emphasis added].

- Cancer-Use slope factors (also referred to as cancer potency factors) combined with weight-of-evidence ratings for carcinogenicity. If a slope factor is not available for a substance, use its ED₁₀ value to estimate a slope factor as follows:

$$\text{Slope factor} = \frac{1}{6(\text{ED}_{10})}$$

- Noncancer toxicological responses of chronic exposure-use reference dose (RfD) values.
- Noncancer toxicological responses of acute exposure-use acute toxicity parameters, such as the LD₅₀.

Assign human toxicity factor values to a hazardous substance using Table 2-4 as follows:

- **If RfD and slope factor values are both available for the hazardous substance, assign the substance a value from Table 2-4 for each. Select the higher of the two values assigned and use it as the overall toxicity factor value for the hazardous substance.** [Emphasis added].
- **If either an RfD or slope factor value is available, but not both, assign the hazardous substance an overall toxicity factor value from Table 2-4 based solely on the available value (RfD or slope factor).** [Emphasis added].
- If neither an RfD nor slope factor value is available, assign the hazardous substance an overall toxicity factor value from Table 2-4 based solely on acute toxicity. That is, consider acute toxicity in Table 2-4 only when both RfD and slope factor values are not available.
- If neither an RfD, nor slope factor, nor acute toxicity value is available, assign the hazardous substance an overall toxicity factor value of 0 and use other hazardous substances for which information is available in evaluating the pathway.

Page 49 of the HRS documentation record at proposal lists a human toxicity factor value of 10,000 for PFOA.

As cited above and in section 3.10.2, PFOA Toxicity, of this support document, HRS Section 2.4.1.1, *Toxicity factor*, instructs that if both an RfD and a cancer slope are available, assign the substance a toxicity factor value from HRS Table 2-4 for each and “[s]elect the higher of the two values assigned and use it as the overall toxicity” (emphasis added). HRS Section 2.4.1.1, *Toxicity factor*, further instructs that, “If either an RfD or slope factor value is available, but not both, assign the hazardous substance an overall toxicity factor value from Table 2-4 **based solely on the available value (RfD or slope factor)**” (emphasis added).

Hence, even if a cancer slope factor value for PFOA was considered and it would have yielded a lower human toxicity factor value in HRS Table 2-4 than for the RfD, the human toxicity factor assigned for HRS scoring purposes based on the RfD would still be required to be used to support the overall HRS human toxicity value of 10,000 for PFOA because it is the highest value. The HRS specifically instructs to use the highest value. (See section 3.10.2, PFOA Toxicity, of this support document.)

According to the *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)* (EPA, 2016) (Reference 13 of the HRS documentation record at proposal), the EPA did assess the carcinogenicity of PFOA. This document states on page 22:

Under EPA's *Guidelines for Carcinogen Risk Assessment* (USEPA 2005a), there is "suggestive evidence of carcinogenic potential" for PFOA. Epidemiology studies demonstrate an association of serum PFOA with kidney and testicular tumors among highly exposed members of the general population. Two chronic bioassays of PFOA support a positive finding for its ability to be tumorigenic in one or more organs of rats, including the liver, testes, and pancreas. EPA estimated a cancer slope factor (CSF) of $0.07 \text{ (mg/kg/day)}^{-1}$ based on testicular tumors.

Considering the cancer slope factor of $0.07 \text{ (mg/kg/day)}^{-1}$ with a weight-of-evidence of "suggestive evidence of carcinogenic potential"⁴⁵ in the Carcinogenicity (Human) section of HRS Table 2-4, *Toxicity Factor Value Evaluation*, this slope factor and weight-of-evidence would fall in the "B" column and the " $0.05 \leq \text{SF} < 0.5$ " category and would be assigned an HRS human toxicity factor value of 100, which is lower than the value of 10,000 assigned to PFOA based on its RfD.

This comment results in no change to the HRS score and no change in the decision to place the Site on the NPL.

3.10.2.3 PFOA Human Epidemiology Studies

Comment: SGPP stated that the EPA should not have assigned an HRS toxicity factor value of 10,000 to PFOA because the EPA "has not identified any epidemiological studies regarding PFOA and potential adverse human health effects that it believes are sufficiently reliable to develop regulatory ground water or drinking water standards."

Response: The HRS toxicity factor of 10,000 for PFOA was correctly based on the RfD as directed by the HRS. Human epidemiological studies or ground water or drinking water standards are not required to be used in assigning the HRS human toxicity value for PFOA. Nor are epidemiological studies required to establish an RfD, which is used to assign a toxicity factor. Although the EPA reviewed and considered human epidemiological data in assessing PFOA toxicity, the human serum PFOA concentrations from the epidemiological studies were not utilized to derive the PFOA RfD because the data lacked the necessary quantitative dose information.

The *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)* (EPA, 2016), which the EPA used to support the assignment of the HRS human toxicity factor value, did provide a summary of a number of human epidemiological studies used to qualitatively examine PFOA toxicity. The human epidemiological studies were not utilized to derive the PFOA RfD because, as explained below, the data lacked the necessary quantitative dose information required if they were to be used in developing an RfD.

The HRS does not specify that the RfD must be derived from human epidemiological studies when selecting an RfD to assign an HRS human toxicity factor value. It only states in HRS Section 2.4.1.1, *Toxicity factor*, to:

Establish human toxicity factor values based on quantitative dose-response parameters for the following three types of toxicity:

- Cancer-Use slope factors (also referred to as cancer potency factors) combined with weight-of-evidence ratings for carcinogenicity. If a slope factor is not available for a substance, use its ED₁₀ value to estimate a slope factor as follows:

⁴⁵ <https://www.epa.gov/fera/risk-assessment-carcinogens>;
https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf

$$\text{Slope factor} = \frac{1}{6(\text{ED}_{10})}$$

- Noncancer toxicological responses of chronic exposure-use **reference dose (RfD) values**. [Emphasis added].
- Noncancer toxicological responses of acute exposure-use acute toxicity parameters, such as the LD₅₀.

The *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)* (EPA, 2016) discusses the human epidemiological studies in section 3.1, Human Studies, beginning on page 79 of Reference 13 of the HRS documentation record at proposal. With specific regard to use of epidemiological studies in the derivation of the RfD, the document states on page 254:

As explained previously, human data identified significant relationships between serum levels and specific indicators of adverse health effects **but lacked the exposure information for dose-response modeling. For this reason none of the human studies provided an appropriate POD for RfD derivation.** The pharmacokinetically-modeled average serum values from the animal studies are restricted to the animal species selected for their low dose response to oral PFOA intakes. Extrapolation to humans adds a layer of uncertainty that needs to be accommodated in deriving the RfD. [Emphasis added].

In Section 4.1.2, RfD Selection, of the *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)* (EPA, 2016), it states on page 257:

There are extensive human data from epidemiology studies on the general population, as well as worker cohorts. The epidemiology data provide support for the human relevance of the hazards identified in the laboratory animals. **However, they lack the quantitative information on the human exposures (doses and durations) responsible for the human serum levels.** Although some associations show a relationship between effects and serum measures, the serum measures are lower than the PODs from the animal studies and some associations are confounded by reverse causality. Data supporting a first-order kinetic relationship between dose/duration and serum concentrations are needed before the human data can be used in a manner comparable to the process utilized in the RfD derivation. [Emphasis added].

Peer Review Charge Questions and Epidemiological Studies

The use of PFOA human serum levels available in epidemiological studies instead of serum levels from animal studies as the data from which the RfD should be derived was addressed in charge questions 1⁴⁶, 2⁴⁷, 3⁴⁸ and 4⁴⁹ posed to external panel reviewers for the *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)* used by the EPA to establish the RfD. Based on peer reviewer panel comments, that the EPA can in some cases

⁴⁶ Charge Question 1 - Studies Used for Quantification: Please comment on the strengths, weaknesses, and characterization of the studies selected as key for quantification.

⁴⁷ Charge Question 2- Additional References: Please provide citations (and, where possible, pdfs or hard copies) for any references you suggest EPA consider adding to the document. Describe where you suggest these references be incorporated.

⁴⁸ Charge Question 3 - Use of Epidemiology Data: The OW [Office of Water] concluded that the human epidemiology data for PFOS/PFOA do not provide adequate quantifiable dose-response information for use as the basis of a candidate RfD because of uncertainty regarding the routes, levels and timing of exposures plus the confounding influences of other PFCs present in serum. Please comment on the OW characterization of the data.

⁴⁹ Charge Question 4 - Characterization of Epidemiology Data: Please comment on the transparency and characterization of the epidemiological data.

consider epidemiological data or not consider these studies in cases in which the epidemiological data are not sufficiently robust for quantifying an RfD, the EPA responded by updating its review of human epidemiological data and explained that the human studies are used qualitatively as a line of evidence to support the health effects assessment. (See Appendix A: *EPA Response to External Peer Review Comments*.) As stated previously, the EPA continued to use the animal data that had serum concentrations corresponding to an administered dose to derive the RfD.

This comment results in no change to the HRS score and no change in the decision to place the Site on the NPL.

3.11 Targets

Comment: SGPP raised several issues with the HRS factor values associated with the level of contamination and the number of individuals (Targets) identified as exposed to contamination released from the SGPP facility. SGPP stated that there are no Level I concentrations attributable to the Site and the status and pumping capacity of well PSW 6 was inaccurately represented in the HRS scoring of the Site, thus the resulting population associated with well PSW 6 was not accurately apportioned. SGPP's comments regarding the targets associated with well PSW 6 are discussed in the following subsections:

- 3.11.1 Level I Concentrations
- 3.11.2 Nearest Well
- 3.11.3 PSW 6 Population

3.11.1 Level I Concentrations

Comment: SGPP contended that there are no Level I concentrations attributable to the Site in any target well. SGPP asserted that, the available data do not support the EPA's assumption that the low level of vinyl chloride detected in PSW 6 is attributable to low levels of TCE at the Site.

Response: A Level I concentration of vinyl chloride was correctly identified at the Site in drinking water well PSW 6. As explained below, for HRS purposes Level I contamination occurs when the concentration of an HRS hazardous substance is present, in a sample meeting observed release criteria, and that concentration is above an applicable HRS identified benchmark. An observed release of vinyl chloride was correctly identified occurring at this site, including attribution of the significant increase of the vinyl chloride concentration and the concentration of vinyl chloride establishing this observed release is above the HRS benchmark associated with the cancer risk screening concentration. See section 3.9, Observed Releases, in this support document.

HRS Sections 3.3.2.1, *Level of contamination*, and 2.5, *Targets*, and its subsections contain the requirements for identifying Level I concentrations. HRS Section 3.3.2.1, *Level of contamination*, of the ground water migration pathway gives the general requirement to identify levels of contamination in the ground water migration pathway. It states:

Evaluate the population served by water from a point of withdrawal based on the level of contamination for that point of withdrawal. Use the applicable factor: Level I concentrations, Level II concentrations, or potential contamination. . . . if one or more samples meet the criteria for an observed release for the point of withdrawal, determine which factor (Level I or Level II concentrations) applies to that point of withdrawal as specified in sections 2.5.1 and 2.5.2. Use the health-based benchmarks from Table 3-10 in determining the level of contamination.

Table 3-10 of the HRS lists the screening concentration for cancer as a drinking water health-based benchmark for evaluating Level I concentrations of drinking water. It is as follows:

TABLE 3-10—HEALTH-BASED BENCHMARKS FOR HAZARDOUS SUBSTANCES IN DRINKING WATER

- Concentration corresponding to Maximum Contaminant Level (MCL).
- Concentration corresponding to a nonzero Maximum Contaminant Level Goal (MCLG).
- Screening concentration for cancer corresponding to that concentration that corresponds to the 10^{-6} individual cancer risk for oral exposures.
- Screening concentration for noncancer toxicological responses corresponding to the Reference Dose (RfD) for oral exposures.

HRS Section 2.5, *Targets*, provides the instructions for determining whether targets are subject to actual contamination at Level I and Level II concentrations. It states:

-Level I:

-Media-specific concentrations for the target meet the criteria for an observed release (or observed contamination) for the pathway and are at or above media-specific benchmark values. These benchmark values (see section 2.5.2) include both screening concentrations and concentrations specified in regulatory limits (such as Maximum Contaminant Level (MCL) values), or

...

Level II:

-Media-specific concentrations for the target meet the criteria for an observed release (or observed contamination) for the pathway, but are less than media-specific benchmarks.

...

HRS Section 2.5.1, *Determination of level of actual contamination at a sampling location*, provides instructions for determining whether Level I or Level II concentrations apply at a sampling location. It states:

Determine whether Level I concentrations or Level II concentrations apply at a sampling location (and thus to the associated targets) as follows:

- Select the benchmarks applicable to the pathway (or threat) being evaluated.
- Compare the concentrations of hazardous substances in the sample (or comparable samples) to their benchmark concentrations for the pathway (or threat), as specified in section 2.5.2.
- Determine which level applies based on this comparison.
- If none of the hazardous substances eligible to be evaluated for the sampling location has an applicable benchmark, assign Level II to the actual contamination at that sampling location for the pathway (or threat).

In making the comparison, consider only those samples, and only those hazardous substances in the sample, that meet the criteria for an observed release (or observed contamination) for the pathway, ...

HRS Section 2.5.2, *Comparison to benchmarks*, explains which benchmarks need to be at or exceeded to be considered Level I concentrations. It states:

Use the following media-specific benchmarks for making the comparisons for the indicated pathway (or threat):

- Maximum Contaminant Level Goals (MCLGs)—ground water migration pathway and drinking water threat in surface water migration pathway. Use only MCLG values greater than 0.
- Maximum Contaminant Levels (MCLs)—ground water migration pathway and drinking water threat in surface water migration pathway.
-
- Screening concentration for noncancer toxicological responses corresponding to the RfD for inhalation exposures (air migration pathway) or for oral exposures (ground water migration pathway; drinking water and human food chain threats in surface water migration pathway; and soil exposure pathway).

Select the benchmark(s) applicable to the pathway (or threat) being evaluated as specified in sections 3 through 6. Compare the concentration of each hazardous substance from the sampling location to its benchmark concentration(s) for that pathway (or threat). Use only those samples and only those hazardous substances in the sample that meet the criteria for an observed release (or observed contamination) for the pathway. . . . If the concentration of any applicable hazardous substance from any sample equals or exceeds its benchmark concentration, consider the sampling location to be subject to Level I concentrations for that pathway (or threat). If more than one benchmark applies to the hazardous substance, assign Level I if the concentration of the hazardous substance equals or exceeds the lowest applicable benchmark concentration.

As identified in section 3.9, Observed Releases, and its subsections of this support document, the HRS documentation record at proposal established an observed release of vinyl chloride.

Pages 37-38 and 50 of the HRS documentation record at proposal establish that the HRS criteria for identifying Level I concentration in a target well have been met. Pages 37-38 of the HRS documentation record at proposal document that vinyl chloride was found at a concentration of 1.3 µg/L in a sample from well PSW 6. SGPP does not dispute vinyl chloride was present at this concentration.

Page 50 of the HRS documentation record at proposal states:

Applicable benchmarks for the hazardous substance detected in the observed release are as follows; **boldface type** denotes the lowest applicable benchmark concentration for each hazardous substance):

TABLE 28. HRS BENCHMARKS – GROUND WATER PATHWAY				
Substance	MCL	Cancer Risk	Non-Cancer Risk	Reference(s)
VC	2	2.1 x 10⁻²	60	2, p. 4
PFOA*	N/A	N/A	N/A	N/A

Concentrations presented in micrograms per liter (µg/L) for consistency with reported analytical data.

*Superfund Chemical Data Matrix (SCDM) benchmarks for PFOA have not been established.

TABLE 29. LEVEL I CONCENTRATIONS						
Well	Sample	Substance	Conc. (µg/L)	RDL* (µg/L)	Benchmark (µg/L)	Reference(s)
Village Well 6	SGPP-DW03	VC	1.3	0.50	2.1×10^{-2}	2, p. 4; 22, p. 38; 23, p. 152; 43, pp. 3–6, 39, 117; 48, pp. 7, 68

µg/L = micrograms per liter

*The RDL for each result is the CRQL adjusted for sample and method [Ref. 33, p. 8]. Since the samples were analyzed through CLP, these adjusted CRQLs are used in place of the HRS-defined sample quantitation limit SQL [Ref. 1, Sections 1.1 and 2.3].

As identified on page 50 of the HRS documentation record at proposal and page 4 of Reference 2⁵⁰ of the HRS documentation record at proposal, the vinyl chloride cancer risk screening concentration for drinking water is 2.1×10^{-2} µg/L (or 2.1×10^{-5} mg/L)). Therefore, the concentration of vinyl chloride in the PSW 6 well sample is above a health-based HRS benchmark and correctly identified as a Level I concentration. SGPP does not dispute the vinyl chloride cancer risk screening concentration for drinking water.

This comment results in no change to the HRS score and no change in the decision to place the Site on the NPL.

3.11.2 Nearest Well

Comment: In challenging the presence of a Level I concentration, SGPP indirectly challenged the assignment of the HRS Nearest Well factor value, which is based on the presence of Level I concentrations in a drinking water well. SGPP contended that there are no Level I Concentrations attributable to the Site in any target wells because the available data do not support that the low level of vinyl chloride detected in drinking water well PSW 6 is attributable to low levels of TCE at the Site. In addition, SGPP identified that this well is not in regular use and is used for emergency backup purposes only, and SGPP questioned its use in the HRS evaluation.

Response: The EPA correctly assigned a factor value of 50 to the Nearest Well factor value based on the presence of Level I concentration of vinyl chloride in a drinking water well. A Level I concentration of vinyl chloride was correctly based on a sample from drinking water well PSW 6 containing vinyl chloride meeting observed release criteria and being above an HRS benchmark as demonstrated above in section 3.11.1, Level I Concentrations, of this support document.

To determine what qualifies as a target in the ground water pathway, HRS Section 3.3, *Targets*, instructs the scorer to:

[e]valuate the targets factor category for an aquifer based on four factors: nearest well, population, resources, and Wellhead Protection Area. Evaluate these four factors based on targets within the target distance limit specified in section 3.0.1.1 and the aquifer boundaries specified in section 3.0.1.2. Determine the targets to be included in evaluating these factors for an aquifer as specified in section 3.0.

⁵⁰ Reference 2 of the HRS documentation record at proposal: EPA. Superfund Chemical Data Matrix (SCDM) Query. Substance: cis-1,2-Dichloroethylene; Factor Values and Benchmarks: Ground Water Pathway; Substance: Polychlorinated biphenyls; Factor Values and Benchmarks: Ground Water Pathway; Substance: Trichloroethylene; Factor Values and Benchmarks: Ground Water Pathway; and VC; Factor Values and Benchmarks: Ground Water Pathway. Query Accessed June 22, 2016. A complete copy of SCDM is available at <http://www.epa.gov/superfund/superfund-chemical-data-matrix-scdm>.

To evaluate targets for assigning the nearest well factor value, HRS Section 3.3.1, *Nearest well*, states that:

[i]n evaluating the nearest well factor, include both the drinking water wells drawing from the aquifer being evaluated and those drawing from overlying aquifers as specified in section 3.0. Include standby wells in this factor only if they are used for drinking water supply at least once every year.

...

Assign a value for the nearest well factor as follows:

- If one or more drinking water wells is subject to Level I concentrations, assign a value of 50.
- If not, but if one or more drinking water wells is subject to Level II concentrations, assign a value of 45.
- If none of the drinking water wells is subject to Level I or Level II concentrations, assign a value as follows:
 - ...
 - If not, determine the shortest distance to any drinking water well, as measured from any source at the site with a ground water containment factor value greater than 0. Select a value from Table 3–11 based on this distance. Assign it as the value for the nearest well factor.

The EPA documented Level I concentrations of vinyl chloride in PSW 6, and this data is shown on page 50 of the HRS documentation record at proposal. A nearest well factor value of 50 was correctly assigned as listed on page 52 of the HRS documentation record at proposal.

Pages 50 of the HRS documentation record at proposal states:

TABLE 29. LEVEL I CONCENTRATIONS						
Well	Sample	Substance	Conc. (µg/L)	RDL* (µg/L)	Benchmark (µg/L)	Reference(s)
Village Well 6	SGPP-DW03	VC	1.3	0.50	2.1×10^{-2}	2, p. 4; 22, p. 38; 23, p. 152; 43, pp. 3–6, 39, 117; 48, pp. 7, 68

µg/L = micrograms per liter

*The RDL for each result is the CRQL adjusted for sample and method [Ref. 33, p. 8]. Since the samples were analyzed through CLP, these adjusted CRQLs are used in place of the HRS-defined sample quantitation limit SQL [Ref. 1, Sections 1.1 and 2.3].

Page 52 of the HRS documentation record at proposal states:

3.3.1 Nearest Well

As identified in **Section 3.3**, the active drinking water supply wells, Village Wells 6 and 7, for the Village of Hoosick Falls are subject to Level I and Level II concentrations, respectively. Therefore, a nearest well factor value of 50 is assigned [Ref. 1, pp. 51602, 51603].

Nearest Well Factor Value: 50

Regarding SGPP's assertion that well PSW 6 is only an emergency backup well, this does not eliminate this well from being the basis for the nearest well factor value. As quoted above HRS Section 3.3.1, *Nearest well*, standby

wells can be considered in assigning the nearest well value if they are used at least once every year. The EPA has contacted the Village of Hoosick Falls and confirmed that the well is currently used 12 days a year. Appendix B of this support document contains current information from the City on how PSW 6 is used as a standby well. Appendix B of this support document will also be included as Reference 64 of the HRS documentation record at promulgation.

Regarding SGPP's assertions that it finds the TCE and vinyl chloride concentrations "low", these assertions do not refute the observed releases identified at the Site. See sections 3.8, Releases Below Regulatory Limits, and 3.9, Observed Releases, of this support document for further discussion of why the contamination in this well qualifies for consideration. An observed release of vinyl chloride and TCE attributable to the Site has been correctly documented at the Site. (Also, see section 3.11.1, Level I Concentrations, of this support document for discussion of the documentation of Level I concentration of vinyl chloride in PSW 6.)

This comment results in no change to the HRS score and no change in the decision to place the Site on the NPL.

3.11.3 PSW 6 Population

Comment: SGPP challenged the apportionment of population to drinking water well PSW 6 in the HRS documentation record at proposal. SGPP claimed that PSW 6 is used by the Village of Hoosick as an emergency backup well. Therefore, SGPP asserted that the EPA's assumption that the well is used to regularly provide water to 1,333 Village residents is incorrect. SGPP cited to page 3 of SGPP Exhibit 13⁵¹ to support its claim that, "As such, PSW 6 should have been treated as a standby well in the HRS scoring and should not have been assigned the same population as the other Village supply wells." SGPP also cited to SGPP Exhibit 14⁵² to support its comment.

SGPP argued that the ground water pathway HRS score for the Site is flawed due to the EPA's assumption that PSW 6 serves 1,333 people. SGPP stated that the EPA incorrectly "calculated this figure by simply dividing the total service population (4,000) by the number of supply wells (3) in the Village in accordance with HRS guidance providing that a system population should be apportioned equally among the active system components if no single component contributes more than 40 percent of the total system population." SGPP explained that contrary to the EPA's assumption, the Village does not equally rely upon each of its supply wells, and, therefore, the EPA should not have apportioned the system population evenly between the three Village supply wells. (SGPP cited to Reference 28⁵³ of the HRS documentation record at proposal and page 3 of SGPP Exhibit 13). According to SGPP, a July 2015 engineering report prepared by the Village's consultant, MRB Group, states that PSW 6 has a significantly lower pumping capacity than the other two supply wells in the Village (see page 3 of SGPP Exhibit 13). Per SGPP, "[a]s set forth in the MRB Report, PSW 6 has a pumping capacity of only 350 gallons per minute ('gpm'), as opposed to the 900 gpm pumping capacity cited by the EPA in the HRS documentation record." (SGPP also cited to Reference 28 of the HRS documentation record at proposal).

SGPP concluded that the targets factor value assigned on line 8a, Level I concentrations, of the ground water pathway score sheet should be zero, not 13,330. SGPP also concluded that the ground water pathway score for the Site is flawed, and the HRS documentation misrepresents the potential threat posed by the Site.

⁵¹ Exhibit 13 of SGPP comment document is: MRB Group. (July 2015). *Engineering Report for Water Treatment Plant Improvements, MRG Group Project No. 0825.15004*.

⁵² Exhibit 14 of SGPP comment document is: USEPA (November 2012). *Hazard Ranking System Guidance Manual*. Excerpt 7 pages: cover sheet, pages 187, 188, 189, 190, 191, 192.

⁵³ Reference 28 of the HRS documentation record at proposal is: Snyder, Scott, WESTON. Project Note to Saint-Gobain Performance Plastics File, Subject: Village Well Information; with attached references. June 6, 2016.

Response: The HRS documentation record has been revised at promulgation to include the most recent data available to determine the population subject to actual contamination at Level I concentration associated with PSW 6 ground water contamination based on its use as a standby well. The EPA agrees that PSW 6 operates as a standby well and has revised the HRS score for the Site accordingly. Based on information from the Village of Hoosick Falls this well is in regular use on approximately a monthly basis when regular maintenance is being performed on the other two wells; therefore, PSW 6 qualifies as a standby well. However, this change to well PSW 6 does not impact the listing decision as the Site score remains above 28.50.

The Level I population associated with drinking water well PSW 6 has been revised in the HRS documentation record at promulgation to reflect the use of this well as a standby well consistent with HRS Section 3.3.2, *Population*, which provides directions on evaluating the population factor.

HRS Sections 3.3.2, *Population*, and 3.3.2.2, *Level I concentrations*, are used to assign a population value for the Site. HRS Section 3.3.2, *Population*, states:

In evaluating the population factor, include those persons served by drinking water wells within the target distance limit specified in section 3.0.1.1. **When a standby well is maintained on a regular basis so that water can be withdrawn, include it in evaluating the population factor.** [Emphasis added].

...

In determining the population served by a well, if the water from the well is blended with other water (for example, water from other ground water wells or surface water intakes), apportion the total population regularly served by the blended system to the well based on the well's relative contribution to the total blended system. In estimating the well's relative contribution, assume each well and intake contributes equally and apportion the population accordingly, except: if the relative contribution of any one well or intake exceeds 40 percent based on average annual pumpage or capacity, estimate the relative contribution of the wells and intakes considering the following data, if available:

- Average annual pumpage from the ground water wells and surface water intakes in the blended system.
- Capacities of the wells and intakes in the blended system.

For systems with standby ground water wells or standby surface water intakes, apportion the total population regularly served by the blended system as described above, except:

- Exclude standby surface water intakes in apportioning the population.
- **When using pumpage data for a standby ground water well, use average pumpage for the period during which the standby well is used** rather than average annual pumpage. [Emphasis added].
- For that portion of the total population that could be apportioned to a standby ground water well, **assign that portion of the population either to that standby well or to the other ground water well(s) and surface water intake(s) that serve that population; do not assign that portion of the population both to the standby well and to the other well(s) and intake(s) in the blended system. Use the apportioning that results in the highest population factor value.** (Either include all standby well(s) or exclude some or all of the standby well(s) as appropriate to obtain this highest value.) Note that the specific standby well(s) included or excluded and, thus, the specific apportioning may

vary in evaluating different aquifers and in evaluating the surface water pathway.
[Emphasis added].

HRS Section 3.3.2.2, *Level I concentrations*, provides the instructions for calculating the Level I concentration factor value. It states:

Sum the number of people served by drinking water from points of withdrawal subject to Level I concentrations. Multiply this sum by 10. Assign this product as the value for this factor. Enter this value in Table 3-1.

The EPA has determined the population factor value as follows:

First, the EPA has determined that well PSW 6 is eligible for consideration at this Site. Well PSW 6 meets the requirements for use in assigning the population factor value for this site because it is used 12 days a year. As quoted above, the HRS states that a standby well can be used in assigning a population factor value if “it is maintained on a regular basis so that water can be withdrawn.” Appendix B of this support document, a January 3, 2017, memorandum between Scott Snyder of Weston Solutions, Inc., the EPA’s contractor, and Jim Hurlburt, Superintendent of the Village of Hoosick Falls municipal water supply, clarifies the use of PSW 6 as a standby well and its pumping during the period when it is used. Appendix B states:

Spoke to Jim Hurlburt of Hoosick Falls Water Department. He confirmed that Village Well 6 is used as an emergency backup well. For maintenance purposes Well 6 is used approximately once per month for approximately thirty to forty minutes at a time. The water pumped from Well 6 is pumped to the pretreatment tank, processed through the water plant, pumped to the clear well, then pumped out to the distribution system. Wells 3 and 7 are disconnected while Well 6 is pumping.

Jim stated that currently, the actual pumping rates of the three village wells are as follows:

Well 7 – 700 gallons per minute (gpm); pumps 365 days/year
Well 3 – 700 gpm; pumps 365 days/year
Well 6 – 300 gpm; pumps 12 days/year [emphasis in original]

Therefore, given the well is used 12 days a year, it is “maintained” for use according to the HRS. In a given year, well PSW 6 provides approximately 144,000 gallons of drinking water to the drinking water system.

Second, the EPA determined the appropriate population to apportion to the standby well. As also identified above, HRS Section 3.3.2, *Population*, directs that a standby well may or may not be used in determining the population factor value:

For that portion of the total population that could be apportioned to a standby ground water well, **assign that portion of the population either to that standby well** or to the other ground water well(s) and surface water intake(s) that serve that population; **do not assign that portion of the population both to the standby well and to the other well(s)** and intake(s) in the blended system. **Use the apportioning that results in the highest population factor value.** (Either include all standby well(s) or exclude some or all of the standby well(s) as appropriate to obtain this highest value.) [Emphasis added].

The EPA included well PSW 6 in the Site scoring because its use results in the highest population factor value.

Third, to determine the appropriate population to assign to this standby well, the EPA next determined the number of wells that supply the Village of Hoosick Falls water system when the standby well is in use. As quoted above, HRS Section 3.3.2, *Population*, states:

- **When using pumpage data for a standby ground water well, use average pumpage for the period during which the standby well is used** rather than average annual pumpage. [Emphasis added].

Based on information from the Village of Hoosick Falls (documented in Appendix B of this support document), when PSW6 is in use, PSW 3 and 7 are turned off allowing PSW 6 to supply 100% of the drinking water to the Village of Hoosick Falls water supply:

For maintenance purposes Well 6 is used approximately once per month for approximately thirty to forty minutes at a time. The water pumped from Well 6 is pumped to the pretreatment tank, processed through the water plant, pumped to the clear well, then pumped out to the distribution system. Wells 3 and 7 are disconnected while Well 6 is pumping.

Therefore, when this standby well is in use the other two wells that supply the Village of Hoosick Falls water system are turned off and well PSW 6 serves all (100%) of the population associated with the Village of Hoosick Falls water supply.

Fourth, the EPA determined the population to assign to well PSW 6. As quoted above, because well PSW 6 is the only well serving the Village of Hoosick Falls municipal water supply while it is in use, the entire population of the Village of Hoosick Falls municipal water supply of 4,000 is apportioned to this well. According to page 50 of the HRS documentation record at proposal, the Village of Hoosick Falls municipal water supply serves an approximate population of 4,000. This information is supported by Reference 8⁵⁴, Population and service connections served by municipal water system; with attached reference, of the HRS documentation record at proposal.

Fifth, to arrive at the final HRS population value, the HRS then considers the level of contamination in the well and weights the population apportioned to that well accordingly. As documented in section 3.11.1, Level I Concentrations, of this support document, the EPA correctly identified Level I concentrations of vinyl chloride in well PSW 6. HRS Section 3.3.2.2, *Level I concentrations*, states:

Sum the number of people served by drinking water from points of withdrawal subject to Level I concentrations. Multiply this sum by 10.

Thus, the 4,000 count apportioned to well PSW 6 is multiplied by 10 to obtain a total of 40,000. This value of 40,000 is then summed with the Level II concentrations value and the Potential contamination value as directed in HRS Sections 3.3.2.3, *Level II concentrations*, and 3.3.2.4, *Potential contamination*. However, both of these values are assigned a 0 value because the entire population served by the Village of Hoosick Falls municipal water supply is considered exposed to Level I concentrations while well PSW 6 is in use and are not double counted as Level II or as potential contamination. Thus, the target population value in the HRS documentation record at promulgation is 40,000.

⁵⁴ Reference 8 of the HRS documentation record at proposal: Snyder, Scott, Weston. Telecon Note: Conversation with Jim Hurlburt, Hoosick Falls Water Department, Subject: Population and service connections served by municipal water system; with attached reference. August 3, 2016.

The HRS documentation record at promulgation was revised to include a total Targets factor value of 40,070 on line 11 of Table 3-1 on page 3 of the HRS documentation record. This total value included the original Resources and Wellhead Protection Area factor values of 0 and 20, respectively, as was proposed.

The EPA notes that, if the EPA had chosen the option of not including drinking water well PSW 6 (a standby well) in the apportioning of the population in the Site scoring, the Site score would remain above 28.50 and continue to qualify for the NPL. In this scenario, although the population apportioned to the standby well would be reduced to 0 and the population, instead, apportioned equally to the two wells in regular use (because they have equal pumping capacity as documented above), the overall site score will remain unchanged. The HRS scoring for the targets associated with the ground water migration pathway would be as follows in this alternative scenario:

<p>Nearest Well: 50*</p> <p>Population</p> <p>Level I Concentrations: 0</p> <p>Level II Concentrations: 2,000**</p> <p>Potential Contamination: 101***, †</p> <p>Population: 2,101</p> <p>Resources: 0†</p> <p>Wellhead Protection Area: 20†</p> <p>Targets: 2,171</p>
<p>Aquifer Score: 100†</p> <p>Ground Water Migration Pathway Score: 100†</p> <p>Site Score 50.00†</p>
<p>*As explained in sections 3.11.1, Level I Concentrations, and 3.11.2, Nearest Well, of this support document, PSW 6 is subject to Level I contamination of vinyl chloride.</p> <p>**The pumping capacity of PSW 3 and 7 are 700 gallons per minute (See Appendix B of this support document). Because in this scenario a well contributes more than 40%, to the Village of Hoosick Falls municipal water supply and PSW 3 and PSW 7 each contributes 50%, the population was apportioned evenly between these 2 wells. That is, 2,000 people for PSW 3 and 2,000 people for PSW 7. (See HRS 3.3.2, <i>Population</i>). In this scenario, PSW 7 is evaluated as a well subject to Level II contamination of PFOA. (See HRS Section 2.5, <i>Targets</i>, which states that actual contamination at Level II concentrations is “[m]edia-specific concentrations for the target meet the criteria for an observed release (or observed contamination) for the pathway, but are less than media-specific benchmarks.”) In this scenario, PSW 7 has an observed release of PFOA but the concentration of PFOA is not evaluated as being above an HRS drinking water benchmark.</p> <p>*** In this scenario, PSW 3 is evaluated as a well subject to potential contamination. The population associated with PSW 3 is evaluated in the “Greater than ¼ to ½” mile distance category of the “Other than karst” section of HRS Table 3-12, <i>Distance-Weighted Population Values for Potential Contamination Factor for Ground Water Migration Pathway</i>. The assigned value for a population of 2,000 is 1,013 which when divided by 10 yields a potential population factor value of 101.3 (rounded to 101). (See HRS Section 3.3.2.4, <i>Potential contamination</i>).</p> <p>† Same value as proposed.</p>

This comment results in no change to the overall HRS score and no change in the decision to place the Site on the NPL.

3.12 HRS Score

Comment: SGPP commented that the HRS site score was inappropriately evaluated in the HRS documentation record at proposal and should be revised. SGPP commented that the population apportioned to PSW6 is incorrect

because this well is a standby well, and, hence, the targets factor value assigned on line 8a, Level I Concentrations, of the ground water pathway scoresheet should be zero, not 13,330 as was assigned for this well at proposal.

Response: The HRS documentation record has been revised at promulgation to consider SGPP's comments and to revise the population associated with well PSW6 according to the HRS. As SGPP commented, well PSW 6 is a standby well that was not properly identified as a standby well at proposal. As explained in detail in section 3.11.3, PSW 6 Population, of this support document, the HRS directs that the entire population be considered in the apportionment of the population associated with PSW 6 when it is operating as a standby well. Therefore, the entire population of the Village of Hoosick Falls municipal water supply is considered when this standby well is in operation.

As documented in section 3.9, Observed Release, of this support document, the likelihood of release value of 550 was correctly assigned in the HRS documentation record at proposal. As documented in section 3.10, Waste Characteristics, of this support document, both vinyl chloride and PFOA receive a toxicity/mobility factor value of 10,000 and because Level I targets are appropriately evaluated (or, even if PFOA is the only hazardous substance evaluated at the Site, Level II targets are present) the waste quantity remains at 100 and the waste characteristics factor category value remains at 32 at promulgation.

Scoring the Site on either vinyl chloride or PFOA results in the Likelihood of Release and Waste Characteristics factor category values remaining unchanged at promulgation. Scoring well PSW 6 as subject to Level I contamination (see section 3.11.1, Level I Concentrations, of this support document) results in an assigned Level I concentration population value of 40,000. SGPP did not challenge that well PSW6 is located within ¼-mile of the Site sources and the nearest well remains at 50. SGPP did not comment on the wellhead protection area and the total targets at promulgation have been revised to 40,070. Therefore, as shown in the revised summary scoresheets below, the ground water migration pathway remains scored at 100.00 in the HRS documentation record at promulgation.

However, as discussed in section 3.11.3, PSW 6 Population, above in this support document, even if no population is apportioned to standby well PSW 6, the population subject to Level II and potential contamination in the remaining wells (well PSW 7 and well PSW 3, respectively) is sufficient to score the Site above 28.50 and continue to qualify for the Site for NPL. In this scenario, there is no population subject to Level I contamination, but a population of 2,000 would be subject to Level II contamination in well PSW7 and an additional population using well PSW 3 would be subject to potential contamination. SGPP did not challenge the location of the nearest well or the wellhead protection area, and those values would remain the same at promulgation. As shown in the revised summary scoresheets below, even if a population of 0 is apportioned to well PSW 6 in the HRS evaluation, the ground water migration pathway would remain scored at 100.00 in the HRS documentation record at promulgation.

Table 3-1, Revised Summary of Ground Water Migration Pathway Scoresheets

Factor Categories and Factors	Maximum Value	Value Assigned in HRS documentation record at Proposal	Value Assigned in HRS documentation record at promulgation	Value Assigned for the Scenario for when Well PSW6 is Not Considered in the HRS Population Evaluation at Promulgation
Likelihood of Release to an Aquifer:	550	550	550 ^(A)	550 ^(A)
Waste Characteristics:				
4. Toxicity/Mobility	(a)	10,000	10,000 ^(B)	10,000 ^(B)
5. Hazardous Waste Quantity	(a)	100	100 ^(B)	100 ^(B)
6. Waste Characteristics	100	32	32 ^(B)	32 ^(B)
Targets:				
7. Nearest Well	50	50	50 ^(C)	50 ^(C)
8. Population:				
8a. Level I Concentrations	(b)	13,330	40,000 ^(D)	0
8b. Level II Concentrations	(b)	1,333	0 ^(E)	2,000 ^(M)
8c. Potential Contamination	(b)	101	0 ^(F)	101 ^(N)
8d. Population (lines 8a + 8b + 8c)	(b)	14,814	40,000 ^(G)	2,101 ^(O)
9. Resources	5	0	0 ^(H)	0 ^(H)
10. Wellhead Protection Area	20	20	20 ^(I)	20 ^(I)
11. Targets (lines 7 + 8d + 9 + 10)	(b)	14,834	40,070 ^(J)	2,171 ^(P)
Ground water Migration Score for an Aquifer:				
12. Aquifer Score [(lines 3 x 6 x 11)/82,500] ^c	100	100	100 ^(K)	100 ^(K, Q)
Ground water Migration Pathway Score				
13. Pathway Score (S_{gw}), (highest S_{gw} value from line 12 for all aquifers evaluated) ^c	100	100	100 ^(L)	100 ^(L, R)

^a Maximum value applies to waste characteristics category.

^b Maximum value not applied.

^c Do not round to nearest integer.

(A) The Likelihood of Release assigned value of 550 remains the same as proposed for both scoring scenarios. (See pages 33 to 48 of the HRS documentation record at proposal and at promulgation. See also section 3.9, Observed Releases, of this support document.)

(B) The Waste Characteristics assigned value of 32 remains the same as proposed for both scoring scenarios. (See page 49 of the HRS documentation record at proposal and at promulgation. See also sections 3.10, Waste Characteristics, and 3.11.1, Level I Concentrations, of this support document.)

(C) The Nearest Well assigned value remains the same as proposed for both scoring scenarios. (See pages 50 and 52 of the HRS documentation record at proposal and at promulgation. See also section 3.11.2, Nearest Well, of this support document.)

(D) The HRS documentation record has been revised at promulgation to include a Level I Concentrations population assigned value of 40,000. Well PSW 6 is a standby well that provides 100% of the drinking water while in operation (that is PSW 3 and PSW 7 are turned off when PSW 6 is being used). Therefore, according to the HRS, the total population associated with the Village of Hoosick Fall municipal water supply (4,000) is apportioned to PSW6 which when multiplied by 10 yields a Level I Concentrations population assigned value of 40,000. (See sections 3.11.1, Level I Concentrations, and 3.11.3, PSW 6 Population, of this support document.)

(E) The HRS documentation record has been revised at promulgation to include a Level II population of 0 to PSW 7 because when well PSW 6 is in operation it provides 100% of the drinking water (i.e., PSW 3 and PSW 7 are turned off when PSW 6 is being used). Therefore, the total population associated with the Village of Hoosick Fall municipal water supply is apportioned to PSW 6. However, it still remains that PSW 7 is contaminated at Level II concentrations, although the scoring at promulgation assigns a population value of 0 to the Level II concentration population to avoid double counting the targets. (See section 3.11.3, PSW 6 Population, of this support document. See also pages 50 and 52 of the HRS documentation record at proposal and at promulgation.)

(F) The HRS documentation record has been revised at promulgation to include a Potential Contamination population assigned value of 0 because when well PSW 6 is in operation it provides 100% of the drinking water (i.e., PSW 3 and PSW 7 are turned off when PSW 6 is being used). Therefore, the total population associated with the Village of Hoosick Fall municipal water supply is apportioned to PSW6. Although the scoring at promulgation assigns a population value of 0 to the Potential Contamination population to avoid double counting targets, well PSW 3 remains subject to potential contamination for HRS scoring purposes. (See section 3.11.3, PSW 6 Population, of this support document. See also pages 50 and 52 of the HRS documentation record at proposal and at promulgation.)

(G) The HRS documentation record has been revised at promulgation to include the sum of the Population as 40,000 (40,000 for Level I + 0 for Level II + 0 for Potential Contamination).

(H) The Resources assigned value remains the same as proposed. (See page 53 of the HRS documentation record at proposal and at promulgation.)

(I) The Wellhead Protection Area assigned value remains the same as proposed. (See page 53 of the HRS documentation record at proposal and at promulgation.)

(J) The HRS documentation record has been revised at promulgation to include the sum of the Targets (40,000 for the Population + 50 for nearest well + 20 for Wellhead Protection Area = 40,070).

(K) The overall ground water migration pathway score for the aquifer remains the same as proposed.

(L) The overall ground water migration pathway score for the Site remains the same as proposed.

(M) In this alternative scenario, PSW 7 is evaluated as a well subject to Level II contamination of PFOA; PSW 7 has an observed release of PFOA, but the concentration of PFOA is not evaluated as being above an HRS drinking water benchmark. The pumping capacity of PSW 3 and 7 is each 700 gallons per minute. (See Appendix B of this support document.) Because in this scenario a well contributes more than 40%, to the Village of Hoosick Falls municipal water supply and PSW 3 and PSW 7 each contributes 50%, the population was apportioned evenly between these 2 wells. That is, the total population of the Village of Hoosick Falls water supply would be apportioned as follows: 2,000 people for PSW 3 and 2,000 people for PSW 7. (See HRS Section 3.3.2, *Population*. See section 3.11.3, PSW 6 Population, of this support document and pages 50 and 52 of the HRS documentation record at proposal.)

(N) In this alternative scenario, even if PSW 3 is evaluated as a well subject to Potential Contamination the pumping capacity of PSW 3 and 7 is each 700 gallons per minute. (See Appendix B of this support document.) In this scenario, a well contributes more than 40% to the Village of Hoosick Falls municipal water supply, and PSW 3 and PSW 7 each contributes 50%, therefore, the population would be apportioned evenly between these 2 wells. That is, the total population of the Village of Hoosick Falls water supply would be apportioned as follows: 2,000 people for PSW 3 and 2,000 people for PSW 7. The population (2,000) associated with PSW 3 is evaluated in the “Greater than $\frac{1}{4}$ to $\frac{1}{2}$ ” mile distance category of the “Other than karst” section of HRS Table 3-12, Distance-Weighted Population Values for Potential Contamination Factor for Ground Water Migration Pathway. The assigned value for a population of 2,000 is 1,013 which when divided by 10 yields a potential population factor value of 101.3 (rounded to 101). (See HRS Section 3.3.2.4, *Potential contamination*. See section 3.11.3, PSW 6 Population, of this support document and pages 50 and 52 of the HRS documentation record at proposal.)

(O) In this alternative scenario, the sum of the Population would be 2,101, (0 for Level I + 2,000 for Level II Concentrations + 101 for Potential Contamination). (See section 3.11.3, PSW 6 Population, of this support document.)

(P) In this alternative scenario, the sum of the Targets would be 2,171 (2,101 for Population + 50 for Nearest Well + 20 for Wellhead Protection Area = 2,171). (See section 3.11.3, PSW 6 Population, of this support document.)

(Q) In this alternative scenario, the overall ground water migration pathway score for the aquifer would remain the same as proposed.

(R) In this alternative scenario, the overall ground water migration pathway score for the Site would remain the same as proposed.

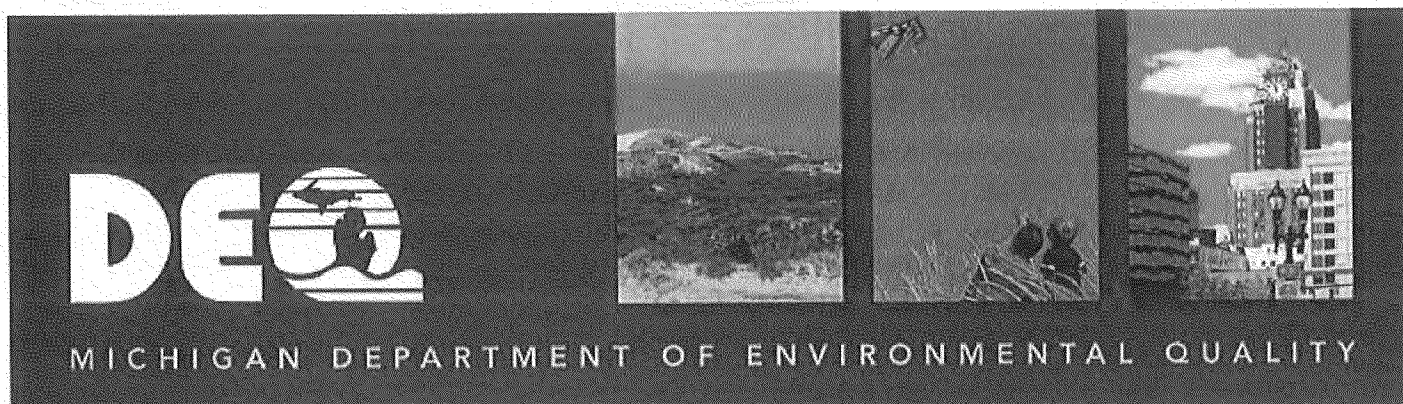
These comments result in no change to the overall HRS score and no change in the decision to place the Site on the NPL.

4. Conclusion

The original HRS score for this site was 50.00. Based on the above responses to comments, while HRS population factor values have been revised, the overall site score remains unchanged. The final scores for the Saint-Gobain Performance Plastics site are:

Ground Water:	100.00
Surface Water:	Not Scored
Soil Exposure:	Not Scored
Air:	Not Scored
HRS Site Score:	50.00

Exhibit F



FOR IMMEDIATE RELEASE

January 9, 2018

Contact:

Melanie Brown, MDEQ Communications, brownm45@michigan.gov, 800-662-9278

Tiffany Brown, MDEQ Public Information Officer, brownt22@michigan.gov, 800-662-9278

State Takes Action to Strengthen Environmental Criteria in Response to PFAS Contamination

Michigan sets new standard of 70 parts per trillion, mirroring federal advisory level

LANSING – Today the Michigan Department of Environmental Quality (MDEQ) announced it has developed a drinking water criterion for perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS). The residential and nonresidential drinking water criterion is 0.07 µg/L (70 parts per trillion) for the combined concentrations of PFOA and PFOS, which sets an official state standard for acceptable concentrations of these contaminants in ground water used for drinking water purposes.

This combined criterion will take effect January 10, 2018. Previously there has been no level set in state criteria.

“This new standard allows us to take regulatory enforcement actions, something we have not been able to do absent a state criterion,” said Heidi Grether, DEQ director. “This means we will now have tools to mandate a responsible party conduct activities to address PFOA and PFOS contamination, thereby reducing risk to human health and the environment.”

With the new criterion, the department can now issue violation notices and take legal action against any responsible party who doesn’t comply with the state’s clean up rules.

“Our philosophy is that we expect responsible parties to voluntarily comply with state clean up criteria, which is why we work in close collaboration with them to help bring them into compliance,” said Grether. “This rule update allows us the proper enforcement tools to ensure state law is met on the occasion that we need them, should compliance become a challenge.”

The legal basis for development of the generic cleanup criteria is Part 201, Environmental Remediation, of the Natural Resources and Environmental Protection Act, 1994 PA 451, as amended, and the Part 201 administrative rules. Rule provisions [R 299.6(9) et al] allow the department to determine that a substance not listed in the generic cleanup criteria tables is a hazardous substance using best available information about toxicological and physical-chemical properties of the substance, and to use that information to develop a generic criterion. The new criterion developed pursuant to these rules take effect when published and announced by the MDEQ.

The PFOA and PFOS drinking water criterion is set at the lifetime health advisory value presented in the United States Environmental Protection Agency Drinking Water Health Advisories for Perfluorooctanoic Acid (PFOA), EPA 822-R-16-005, May 2016 and Perfluorooctane Sulfonate (PFOS), EPA 822-R-16-004, May 2016. Compliance with the drinking water criterion requires comparing the sum of the PFOA and PFOS groundwater concentrations to the drinking water criterion of 0.07 µg/L. The drinking water criterion for PFOA and PFOS protect for both short-term developmental and chronic exposures.

Last fall Governor Snyder issued Executive Directive 2017-4 creating the Michigan PFAS Action Response Team (MPART) to address the need for cooperation and coordination among agencies at all levels of government charged with identifying PFAS contamination, informing and empowering the public, and mitigating the potential effects. Particularly in view of the current lack of nationwide best practices, the directive serves to set a strategic and proactive approach for the state with this emerging contaminant. The MDEQ has been a key agency in the discovery and investigation of PFAS sites around the state with the goal of mitigating potential risk to public health and identifying immediate and long-term solutions to this issue.

“While PFAS is a national issue, we are determined to continue studying this emerging science until we are assured that Michigan’s communities are safe from this contaminant,” said Grether.

###

You are subscribed to Press Releases for Michigan Department of Environmental Quality.

Exhibit G

STATE OF MICHIGAN
CIRCUIT COURT FOR THE COUNTY OF KENT

WOLVERINE SHOE & TANNING)	
CORPORATION, a Michigan)	
corporation.)	Civil Action
)	No. <u>2609</u>
Plaintiff)	
)	
vs)	
)	
)	<u>JUDGMENT</u>
TOWNSHIP OF PLAINFIELD, et al)	
)	
Defendants)	
)	

At a session of said Court held in the
Court House in the City of Grand Rapids, on
the 6th day of May, 1966.

PRESENT: HONORABLE STUART HOPPIUS
 Circuit Judge

The parties of this suit having come to an amicable settlement, and the Court being fully advised in the premises, and approves of said settlement.

NOW THEREFORE, IT IS HEREBY ORDERED AND ADJUDGED:

1. The plaintiff, Wolverine Shoe & Tanning Corporation, is authorized to use that portion of the premises described in paragraph 2 of its Complaint, which is outlined in red on Exhibit A, attached to said Complaint, as a dump for its industrial wastes. It is adjudged that said premises so outlined in red is a nonconforming use within that term as used in the Zoning Ordinance of Plainfield Township, which premises are described as follows:

Commencing on the West line of the E 1/2 of the SW 1/4 of Section 4, Town 8 North, Range 11 West, 1740 feet N of the N boundary line of House Street, thence S along said West line to the North boundary of House Street, thence East along the North line of House Street 1300 feet more or less to the N and S 1/4 line, thence W along said N and S 1/4 line, 1620 feet, thence Northwesterly 1320 feet more or less to beginning, being approximately 50 acres, Plainfield Township, Kent County, Michigan.

2. Authorization to use said premises as a non-conforming use for the purpose of a dump for disposal of the industrial wastes of the plaintiff, is subject to the following conditions:

A. Wolverine Shoe & Tanning Corporation shall conform with the following conditions and provisions:

(1) It shall promptly become licensed by the State Health Department under Act 87 of Public Acts of 1965, to operate said dump.

(2) It shall conform with Act 87 of Public Acts of 1965 and to all rules and regulations adopted thereunder by the Department of Public Health.

(3) It shall conform to any Ordinance of the Township of Plainfield now in effect and/or later hereafter enacted pertaining to dumps.

(4) It shall dispose of industrial solids and liquid wastes in such manner that odors will not unreasonably interfere with the peace and enjoyment of rights of persons in that community, and make such treatment of such industrial wastes as is reasonably possible to eliminate odors therefrom.

(4 1/2) It shall maintain a 10 foot buffer strip of pines or similar shrubs or trees surrounding said premises.

(5) It shall cover sludge and all other industrial wastes, other than liquid wastes, daily.

(6) It shall dump industrial liquor and/or other liquid or semi-liquid wastes only in such places as tests previously taken show will readily absorb the same so that no part of said wastes will remain uncovered over sixty (60) hours.

(7) Transportation of industrial wastes shall be made in a manner that will prevent any of said wastes from spilling from said containers, in transit from the place of business until said waste is dumped in the area above described.

(8) It shall keep the area of said dump and its premises adjoining in such manner that they shall not become unsightly so as to adversely affect the market value of property in the community.

(9) It shall not expand the dump to any other premises from that above described as being authorized as a nonconforming use, except by any variance or rezoning which may be granted in conformance with the Zoning Ordinance of Plainfield Township.

(10) If a public disposal system becomes available, it shall use said system in the disposal of its industrial wastes.

(11) It shall see that water supplies and/or lakes or other waters not owned by the company

will not be contaminated by any use made of said dump.

(12) It shall so use said dump in such manner that it will not afford a breeding place for flies or vermin.

(13) Copies of plans and specifications furnished to any Health Department shall also be furnished to the Township of Plainfield, at the same time such plans are furnished to the Health Department.

(14) It shall make the dump and surrounding area owned by it available for inspection by the Town Board members and/or any of its duly authorized agents and/or attorneys, at any reasonable hours during working days, when requested.

(15) Said dump shall be used for disposal of the industrial wastes only of said company.

(16) Said company will use said dump to the maximum extent for disposal of its industrial wastes consistent with the above provisions.

3. Costs are awarded to neither party as a public question is involved.

4. The temporary injunction issued in said cause is hereby dismissed.


Circuit Judge


James B. Ryan

Approved as to substance and form:

WOLVERINE SHOE & TANNING CORP.
a Michigan corporation, plaintiff

BY 
Its Attorney

TOWNSHIP OF PLAINFIELD, Defendant

BY 
Its Attorney

GEORGE COMSTOCK, GLADYS COMSTOCK,
ANTHONY GEDRITIS, HELEN GEDRITIS,
EDMUND BRODOWSKI, and SOPHIA
BRODOWSKI, Defendants

BY 
their attorney

Exhibit H

3M Chemicals

3M Center
St. Paul, MN 55144-1000
612 733 1110

January 15, 1999

VIA FACSIMILE

Rick DeBlasio
Executive Vice President
Corporate Operations Group
Wolverine Worldwide, Inc.
North Main Office
123 North Main Street
Rockford, MI 49351

Dear Mr. DeBlasio:

This letter is in follow-up to a meeting held at Wolverine Worldwide, Inc. on January 10, 1999.

Thank you for agreeing to meet with 3M's representatives. Although I was not able to attend that meeting, I would like to respond to your request for a written summary of the key points, which are as follows:

- * There is a growing interest in understanding the effects of chemicals on human health and the environment. In this regard, 3M has a comprehensive initiative underway that is helping us to advance the understanding of fluorochemicals. One example is the fluorochemical perfluorooctane sulfonate (PFOS). 3M has manufactured PFOS and related molecules since 1948.
- * PFOS is an example of an "organic" fluorine molecule. Human serum has been known to contain organic fluorine molecules for over thirty years, as reported in the published scientific literature.
- * 3M's improvement in the application of analytical techniques has allowed for rapid analysis of specific organic fluorine molecules at extremely low limits of detection.
- * 3M's state of the art analytical techniques have led to the recent discovery of PFOS at tens of parts per billion (ppb) levels in serum samples of nonoccupationally exposed people.

January 15, 1999

Page 2

* Fluorochemicals such as PFOS are stable molecules and therefore persistent. As such, PFOS has the potential to accumulate in the body with repeated exposures and to resist degradation in the environment. This information was reported to your company previously in an updated Material Safety Data Sheet as recently as late 1998.

* 3M has conducted medical surveillance among employees occupationally exposed to PFOS for over twenty years. These employees have PFOS serum levels that range from one part per million (ppm) up to 12 ppm. No adverse health effect associated with PFOS exposure has been found in 3M employees, whose measured level is about 100 times higher than levels seen in the serum of people without occupational exposure.

* Further, the currently available evidence does not suggest any human health effect associated with the levels of PFOS found in serum samples of people without occupational exposure.

* Exposure could occur from manufacturing processes of 3M and its downstream users, as well as from product use and disposal. The relative contribution of these various sources to population exposure and the routes of exposure are currently under study.

3M has undertaken a wide range of stewardship initiatives in response to these recent findings. These stewardship activities are outlined below:

* 3M is actively developing further human health and toxicological information to advance our scientific understanding. We are working with a number of leading independent researchers and scientists to help with this effort.

* An expansive environmental testing program is underway to advance our understanding of exposure routes to these materials outside as well as within the occupational setting.

* 3M has initiated discussions with regulatory agencies globally, including the U.S. EPA and FDA, to advise them of our findings and to seek their input and assistance with our testing and stewardship initiatives.

* In spite of the absence of known human health effects at the levels observed, 3M is committed to reducing sources of exposure to PFOS. In that regard, we are actively reducing fluorochemical residuals in our



January 15, 1999
Page 3

products and reducing environmental emissions and waste streams at our manufacturing facilities. We are also exploring opportunities to transition from persistent to non-persistent chemistries where appropriate.

* We are committed to keeping our customers fully informed via updates to our Material Safety Data Sheets and product labels, face-to-face meetings and follow-up with 3M internal resources to assist customers with their own industrial hygiene and environmental programs. We are prepared to assist you in communications with your downstream users or customers if you so desire. We will also be communicating this information to some of our downstream customers.

In summary, our efforts are being guided by the concept that reducing unnecessary human and environmental exposure to a persistent chemical is the prudent and responsible thing to do, even in the absence of known human health effects. We hope that you agree and we look forward to working together to implement this objective. We will continue to bring you products and services that embrace 3M's finest traditions of innovation and reliability.

We trust that you appreciate the delicate nature of this information and its potential for misuse. We ask that you treat it accordingly.

Sincerely,



John S. Boyd
Business Director
3M Protective Chemicals Products Division

JSB/kk

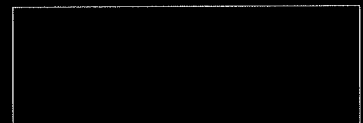


Exhibit I

B R E W E R
ATTORNEYS & COUNSELORS

November 28, 2017

VIA EMAIL

Mr. David Latchana
Associate General Counsel
Wolverine Worldwide, Inc.
9341 Courtland Drive NE
Rockford, MI 49351

Dear David:

I write on behalf of 3M Company ("3M") in connection with misleading statements made by Wolverine World Wide, Inc. ("Wolverine") relating to the environmental presence of certain perfluorochemicals ("PFCs"), commonly referred to as per- and polyfluoroalkyl substances ("PFAS"), in the area of Rockford, Michigan. This letter also responds to your request to attend a community meeting that will reportedly occur on November 29.

Initially, we do not know the purpose of the November 29, meeting. 3M has not been advised of Wolverine's manufacturing or disposal practices, nor should we be. It is our understanding that such practices are under investigation by the company, itself, and state and local regulators. We hope a clarification of what Wolverine knew about PFOS, and when, will assist all parties involved in their respective inquiries. Naturally, 3M is not presently in a position to participate in a public forum relating to Wolverine's manufacturing or disposal practices.

As you know, Wolverine denied its knowledge of certain PFCs, and made unfounded allegations against 3M in a transparent attempt to shift blame for its own environmental practices to 3M. There have been several instances where it appears Wolverine distorted the record to deflect blame for its responsibilities, including, but not limited to, the following:

1. Wolverine reportedly advised the media, regulators, and the general public that it was unaware, until 2016, of PFOS and its use at Wolverine's former tannery in Rockford;
2. Wolverine reportedly claimed it was unfamiliar with 3M's highly-publicized announcement on May 16, 2000, that it was voluntarily phasing out of the production and use of certain PFCs, including PFOS;
3. During a public forum in 2016, involving community leaders and impacted residents, Wolverine attorney Michael Robinson and environmental consultant Mark Westra reportedly stated that there was "no evidence PFOS was ever used at the Rockford Tannery site;"
4. Wolverine reports on its website that it has invited 3M "to step up and partner with us..." and states that Wolverine "has not yet had access to this [PFAS] research;" and

B R E W E R

Mr. David Latchana

November 28, 2017

Page 2

5. In a letter to area residents, dated October 17, 2017, Wolverine writes, "[u]ltimately, 3M Scotchgard should be responsible for any adverse impact from this situation."

For the Record

Wolverine was advised regarding the presence of PFOS in products sold by 3M before, during and after the period of 3M's phaseout announcement in May 2000.

3M representatives met with Wolverine officials, provided detailed information regarding its products sold to Wolverine, and reported 3M's view that PFOS, although not harmful to human health at typical exposure levels, do bioaccumulate and are persistent in the environment.

Not only would Wolverine have been aware of 3M's voluntary phaseout announcement from the global media attention it received, 3M officials met with Wolverine representatives in person two days after the phaseout announcement. This meeting is confirmed in a letter, dated May 22, 2000.

It is not clear why Wolverine claims on its website to have invited 3M to "step up and partner" with the company. However, 3M will not participate in response actions due to the environmental practices of Wolverine.

Contrary to its current statements that Wolverine does not have access to 3M-sponsored research on PFAS, a significant amount of 3M-sponsored research about PFAS is in the public domain. Additionally, in a letter, dated October 23, 2017, 3M directed Wolverine to a "PFC website" that contains summaries of much of this material.

Our company has been at the forefront of working with regulators, researchers, scientists, and community stakeholders all over the world to advance the scientific understanding of these chemistries. This research confirms that PFCs do not present harm to human health or the environment at levels typically found in the environment. We trust Wolverine will avail itself of these many public reports -- to the extent they inform the company's response actions for decades of disposal activities now under investigation.

Finally, 3M bears no legal responsibility for the environmental practices of Wolverine. In our view, to suggest otherwise is reckless, and fails regulators, impacted residents, and the general public working diligently to respond to this environmental concern.

3M has no liability under Michigan law for any damages caused by Wolverine's use of any of its products after said products left 3M's control. Without prejudicing any of its rights under law, 3M requests that Wolverine immediately correct the misinformation in the public

B R E W E R

Mr. David Latchana

November 28, 2017

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domain. Given the impacts of such false representations to our company and other key stakeholders, we expect these actions will include, but not be limited to:

1. We expect Wolverine will write each resident to whom it sent its prior letter, dated October 17, 2017, and properly inform them of the facts; and
2. Issue a public statement which acknowledges that 3M officials personally met with Wolverine representatives for the express purpose of discussing the phaseout announcement – a meeting for which Wolverine apparently now denies responsibility.

Our aim is promote awareness and understanding of these chemistries, and to make sure our customers, employees, regulators, and the public have an informed view of our record of corporate stewardship.

Given the urgency of this situation, its impacts to local citizens, and the continued pursuit of investigative proceedings by regulators, we expect all of the aforementioned corrective measures to be in effect by December 4, 2017.

Thank you for your attention to this matter.

Sincerely,



William A. Brewer III

Cc: Mary Cullen, Esq., 3M Company
Karna Peters, Esq., 3M Company